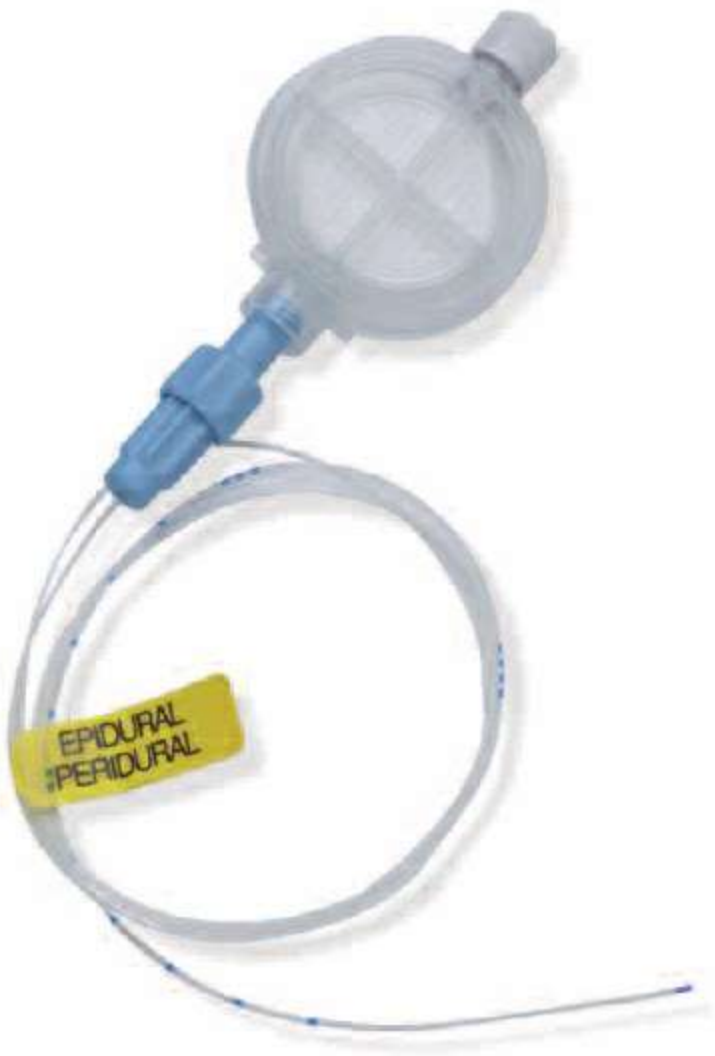


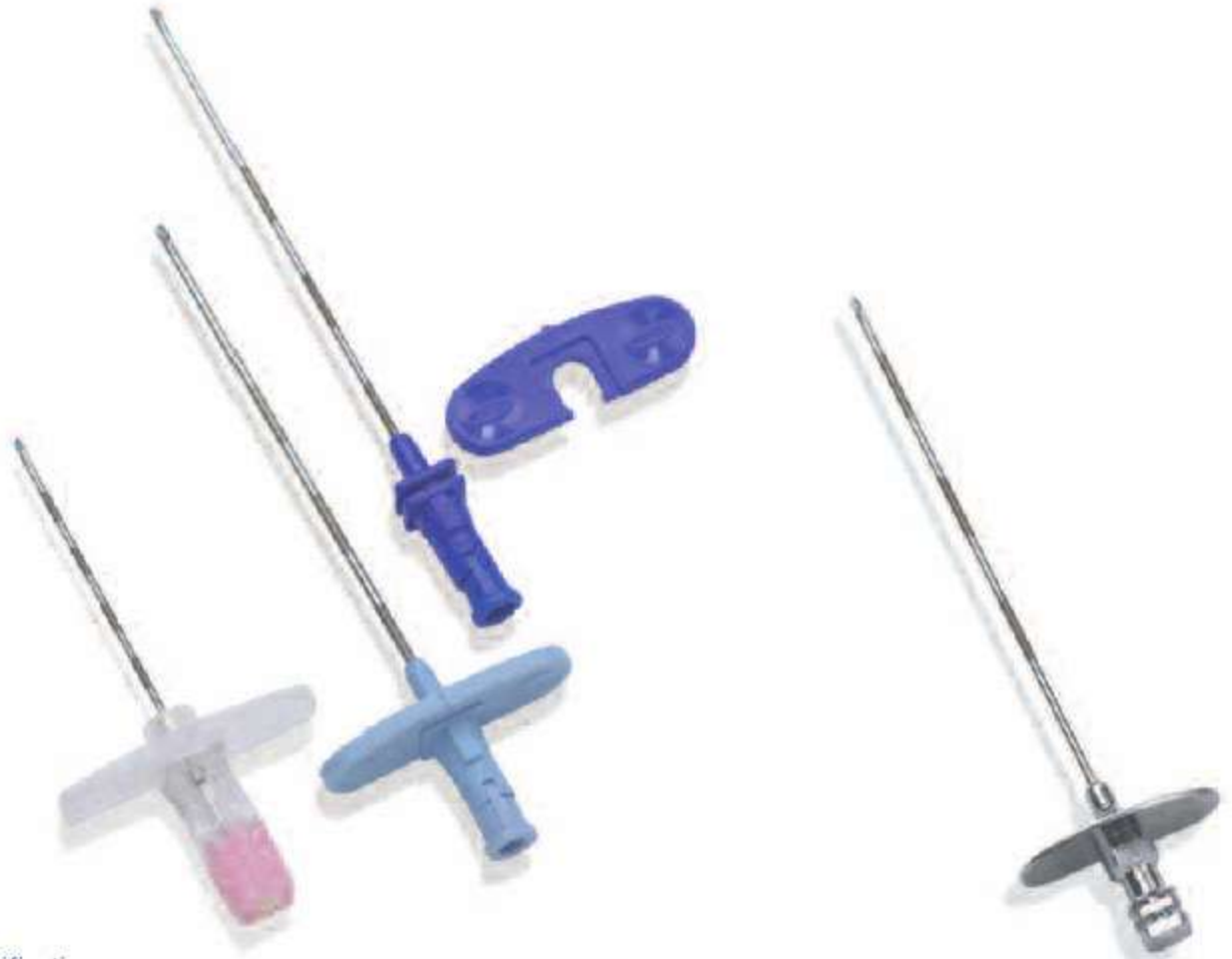
Epidural Anaesthesia

For the past 30 years PORTEX® has pioneered Epidural Systems. After being the first to produce epidural catheters for Obstetric anaesthesia in the early 1970s, PORTEX® went on to develop 'single use' devices in the early 1980s, quickly establishing a strong reputation for innovation, quality and reliability expected from a market leader. The PORTEX® MINIPACK was the first 'single-use' kit designed specifically for epidural procedures and included the first plastic, low friction Loss of Resistance Device. The success of this epidural kit has led to the trade name 'Minipack' being used generically within the medical profession to describe a basic single-use epidural pack.

Today PORTEX® continues to lead the field in epidural anaesthesia with a broad range of epidural procedure kits and components, including LOCKIT®, the unique catheter fixation device launched in 1999 in response to the well-documented incidence of epidural catheter migration during post-operative patient management.

Recognising that procedural techniques vary, PORTEX® has pioneered a custom kitting service, allowing clinicians to customise a procedure tray to suit individual needs.

smiths



Specification

Needle Gauge	Length	Product Code
18G Paediatric	50mm (clear hub)	100/395/018
19G Paediatric	50mm (clear hub)	100/395/019
16G	80mm	100/395/160
18G	80mm	100/395/180
17G	80mm (clear hub)	L727/61 *
18G	80mm (clear hub)	L728/61 *
16G	110mm (clear hub)	100/395/560
18G	110mm (clear hub)	100/395/580

Supplied sterile, individually packed in cartons of 10

* Supplied sterile, individually packed in cartons of 20

Tuohy Needles

Designed to provide accurate and reliable access to the epidural space.

- Optimised tip profile to maximise the all-important feel during insertion.
- Internal stylets minimise tissue coring during insertion.
- Optional snap on wings allow maximum flexibility in use.
- Depth of needle insertion is easily determined by clear 10mm graduations.
- Extra length and paediatric sizes available.

Specification

Needle Gauge	Length	Product Code
16G Winged	80mm	E522*

*Supplied sterile, Individually packed in cartons of 20

All Metal Tuohy Needle

Alternative design of epidural needle featuring an all-metal hub and stylet.

Sharps Safety Devices

Description	Product Code
Point-Lok*	4139

Supplied in packs of 10 x 100

Specification

	Capacity	Product Code
Epidural LORD	10ml	100/398/000

Supplied sterile, individually packed in cartons of 10

Epidural 'Loss of Resistance' Device

The PORTEX® 'Loss of Resistance' Device is a single-use, low-friction syringe specifically designed to facilitate successful location of the epidural space.

- Designed with low and consistent frictional movement of the plunger to provide excellent sensitivity for epidural space detection.
- Graduated barrel indicates degree of plunger advancement.
- Suitable for use with both air and saline techniques with standard Luer slip connection to epidural needles.

Specification

Tuohy Needle Gauge	Length	Product Code
16G	80mm	100/380/016
18G	80mm	100/380/018

Supplied sterile in packs of 10

Epidural Single Shot Packs

'Loss of Resistance' Device and Tuohy needle set. Ideal for use in chronic pain clinics for bolus injections into the epidural space.

Contents: (Tuohy Needle – length 80mm, with attachable wings, a 10ml plastic LORD and a 18G filter needle).

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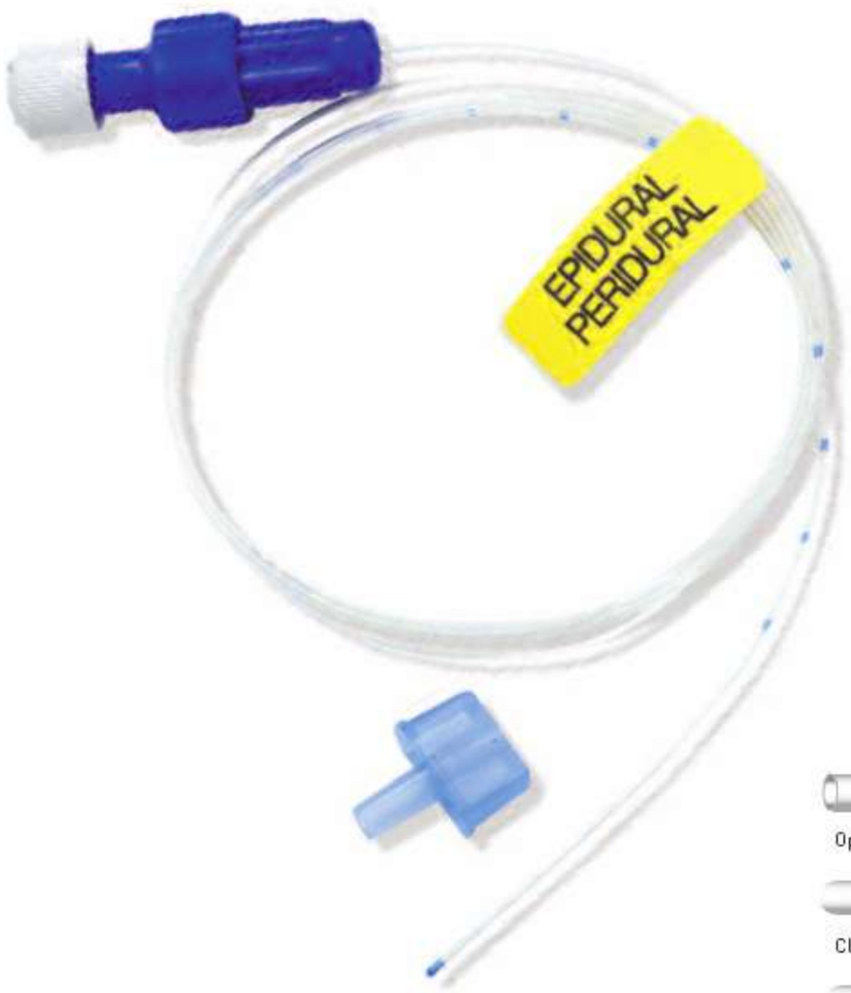

Open End Catheter

Closed End Catheter – 3 Lateral Eyes

Closed End Catheter – 3 Closer Eyes (Paediatric)

Epidural Catheter

- Manufactured from a clear blend of Polyether block amide for optimum clarity, strength and kink resistance.
- Available in various gauges with a choice of distal tip eye geometry.
- Smooth tip forming to minimise trauma during insertion.
- Standard 1cm catheter marking to facilitate accurate catheter positioning.
- Confirmed patency and consistent flow rates achieved through 100% flow testing after manufacture.
- Distal tip mark to aid visual confirmation of complete catheter on removal.
- Paediatric catheters available in 18G or 19G with option of closer, helically placed eyes for even distribution of drugs, reducing likelihood of multi-compartmental spread of local anaesthetic*.
- All catheters are supplied with a Luer lock connector.

* Collier C B. Gatt SP. A new epidural catheter. Closer eyes for safety? Anaesthesia 1993:48; 803-806.

Specification

Clear Catheter Type	For use with needle gauge	Length	Catheter ID Label	Catheter Guide	Catheter Connector	Nominal Diameter mm Internal	External	Product Code
16G Closed End 3 Eyes	16G	915mm	•	•	•	0.55	1.03	100/382/116
16G 3 Closer Eyes	16G	915mm	•	•	•	0.55	1.03	100/382/816
18G Closed End 3 Eyes	18G	915mm	•	•	•	0.45	0 83	100/382/118
18G 3 Closer Eyes	18G	915mm	•	•	•	0.45	0.83	100/382/818
18GHD (Higher Stiffness) Closed End 3 Eyes	18G	915mm	•	•	•	0.45	0.83	100/382/218
19G Paediatric Open End	19G	650mm	•	•	•	0.38	0.63	100/382/019
Catheters gauged to suit the epidural needle through which insertion is intended.								Supplied in packs of 10
19G Open End	16G	915mm		•	•	0.55	1.01	G994/61
19G Closed End 3 Eyes	16G	915mm		•	•	0.55	1.01	G995/61
20G Open End	18G	915mm		•	•	0.46	0.86	G996/61
20G Closed End 3 Eyes	18G	915mm		•	•	0.46	0.86	G997/61
Actual catheter gauge.								Supplied in packs of 10

Specification

Size	Product Code
Tunnelling Device – 200mm & Handle	100/387/020
Tunnelling Device – 350mm & Handle	100/387/035

Supplied sterile and packed individually.

Subcutaneous Tunnelling Device

With the wider application of epidural analgesia in the management of long-term pain relief, the subcutaneous implantation of epidural catheters offers significant advantages to both clinician and patient.

The PORTEX® Subcutaneous Tunnelling Device is a quality, single-use surgical instrument designed to aid the subcutaneous placement of epidural catheters.

- The atraumatic tip prevents damage to the major blood vessels.
- The thin, smooth wall and large internal diameter allows easy passage of the catheter.
- Manufactured from polished surgical quality stainless steel, it can be gently curved to follow the desired pathway through the tissues.
- Offered in a choice of two lengths – 200mm and 350mm to suit individual techniques.
- Subcutaneous implantation reduces the risk of infection in the epidural space, provides security against catheter displacement, particularly in mobile patients, and sites the catheter connection conveniently for infusion of prescribed drugs.

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Specification

Catheter Gauge	Product Code
16G	100/399/016
18G	100/399/018

Supplied sterile in packs of 20

LOCKIT® Epidural Catheter Fixation Device

LOCKIT® is a unique epidural catheter fixation device designed to prevent unwanted catheter migration. LOCKIT® ensures that pain control delivered via the epidural catheter is not compromised, providing increased confidence and peace of mind during post-operative pain management.

- Transparent locking mechanism maintains catheter patency and permits monitoring of catheter exit site.
- Foam adhesive pad makes application easy and minimises patient discomfort.
- Medical grade adhesive layer avoids skin irritation.
- Easy-to-peel backing makes application straightforward, even when wearing gloves.
- Available for both 16G and 18G catheters.

Disc

Flat

Specification

Filter Type	Membrane Pore Size	Maximum Pressure kg/cm²	Filter Area cm²	Priming Volume ml	Product Code
Flat	0.2µm hydrophilic 2-way	7.0	4.91	0.75	100/386/010
Disc	0.2µm hydrophilic 2-way	5.3	2.77	0.36	100/385/010
Flat	0.2µm	5.27	4.3	0.7	G556/61

Supplied sterile, individually packed in cartons of 10.

Epidural Filters, Disc & Flat, with Luer Lock connection

Smiths Medical low volume bacterial filters are available from PORTEX®. These filters may be used for the in-line filtration of low volume doses of aqueous solutions. These are especially suitable for filtration of drug solutions during injection into the epidural space in order to protect the patient from the transmission of infection or other particulate matter.

- The 0.2µm hydrophilic-supported membrane allows two-way filtration and the ability to test aspirate.
- Male and female Luer lock connections for maximum security.
- Flat profile for patient comfort (flat filter only).
- Transparent to allow visual monitoring of filtration and low priming volume.
- Suitable for 96 hours period of use (flat filter only).

N.B. We recommend use of these filters with a syringe no smaller than 10ml capacity to avoid undue pressure.

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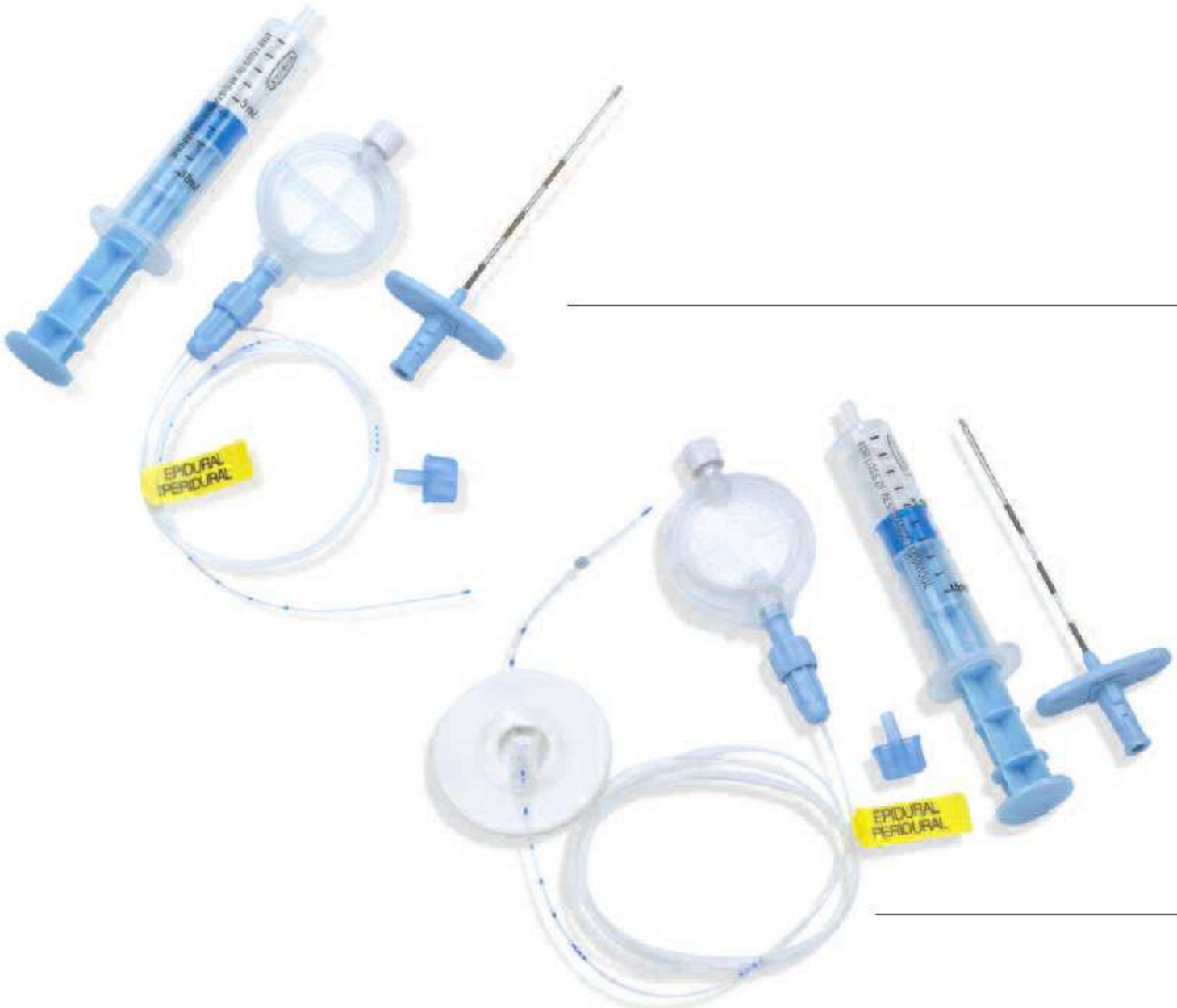


Epidural Minipacks System 1/2/3/4

A cost-effective and convenient procedure pack, containing all the essential components needed to perform an epidural procedure. Available in 4 variants providing flexibility and choice. All products are single-use and offered in space-saving packs.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139

Supplied in packs of 10 x 100

Specification Epidural Minipacks System 1

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Plastic LORD Size	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G	80mm	•	Open End	10ml	•	•	100/391/016
16G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/116
16G	110mm	•	Closed End 3 Eyes	10ml	•	•	100/391/516
16G	80mm	•	Closed End 3 Closer Eyes	10ml	•	•	100/391/816
16G	80mm	•	Closed End 3 Eyes	7ml		•	M477*
17G	80mm	•	Open End	7ml		•	G747*
17G	80mm	•	Closed End 3 Eyes	7ml		•	G998*
18G	80mm	•	Open End	10ml	•	•	100/391/018
18G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/118
18G HD (Higher Stiffness)	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/318
18G	110mm	•	Closed End 3 Eyes	10ml	•	•	100/391/518
18G	80mm	•	Closed End 3 Closer Eyes	10ml	•	•	100/391/818
18G	80mm	•	Open End	7ml		•	G749*
18G	80mm	•	Closed End 3 Eyes	7ml		•	G748*
19G	80mm	•	Open End	10ml	•	•	100/391/190

Supplied in packs of 10 *Supplied in packs of 20

Specification Epidural Minipacks System 1 Paediatric

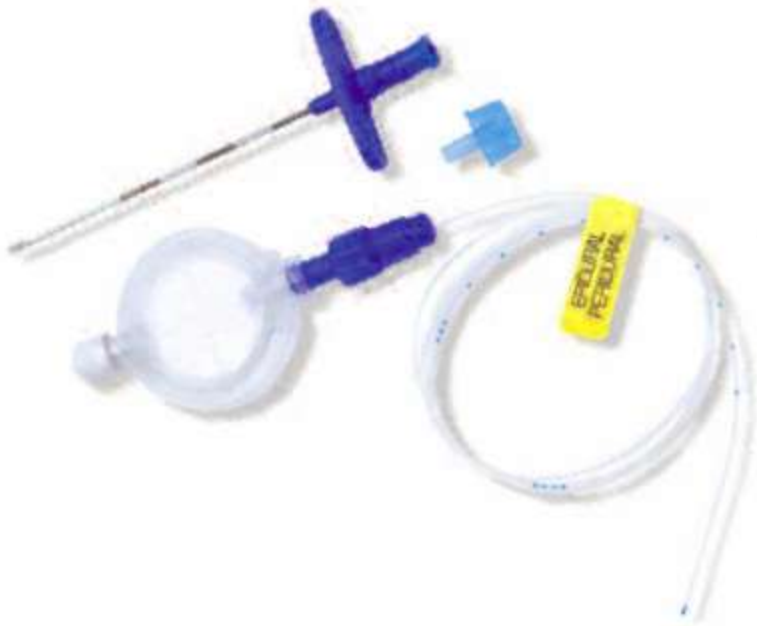
Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Plastic LORD Size	Catheter Identification Label	0.2µm Epidural Filter	Product Code
18G	50mm	•	Closed End 3 Closer Eyes	10ml	•	•	100/391/180
19G	50mm	•	Open End	10ml	•	•	100/391/019

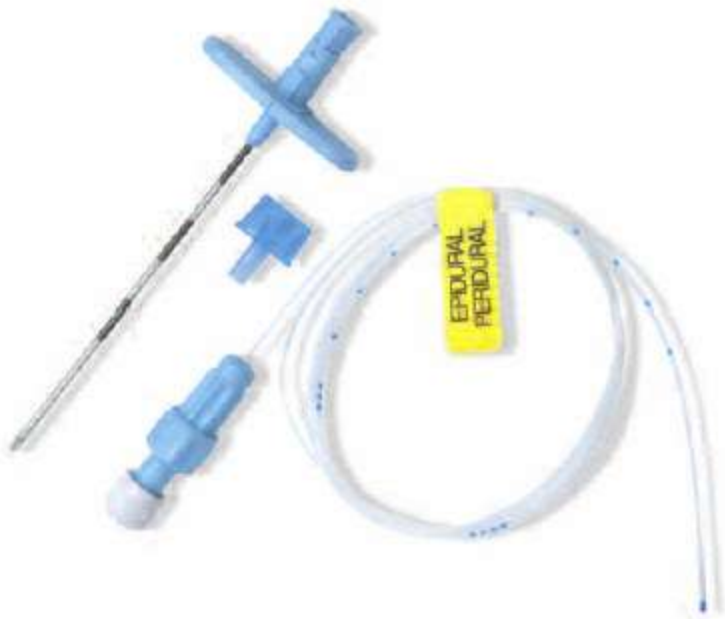
Supplied in packs of 10

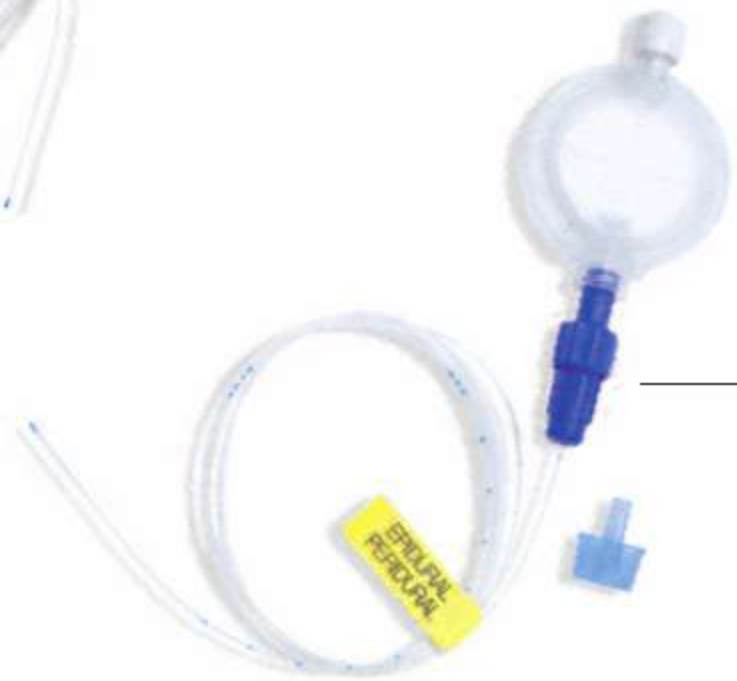
Specification Epidural Minipacks System 1 with LOCKIT® Fixation Device

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Plastic LORD Size	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/716
18G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/718

Supplied in packs of 10







Sharps Safety Devices

Description	Product Code
Point-Lok®	4139

Supplied in packs of 10 x 100

Epidural Minipacks System 2

Specification

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G	80mm	•	Clear Closed End 3 Eyes	•	•	100/392/116*
17G	80mm	•	Clear Open End		•	E623
17G	80mm	•	Clear Closed End 3 Eyes		•	F948
17G	80mm	•	Radio Opaque Closed End 3 Eyes		•	F950
17G	80mm	•	Clear Closed End 3 Eyes		•	M123
18G	80mm	•	Clear Closed End 3 Eyes	•	•	100/392/118*
18G	80mm	•	Clear Closed End 3 Eyes		•	G746
18G	80mm	•	Clear Closed End 3 Eyes		•	F949
18G	80mm	•	Clear Closed End 3 Eyes		•	M125

Supplied in packs of 20 *Supplied in packs of 10

Epidural Minipacks System 3

Specification

Clear Catheter with Connector & Guide	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G Closed End 3 Eyes	•	•	100/393/116
18G Closed End 3 Eyes	•	•	100/393/118

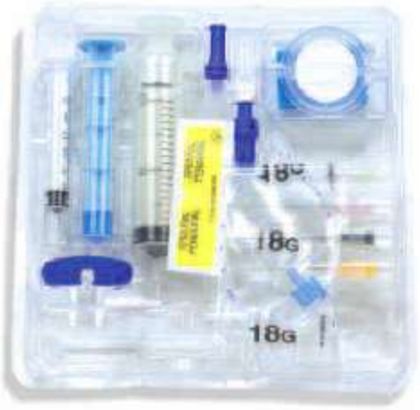
Supplied in packs of 10

Epidural Minipacks System 4

Specification

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Catheter Identification Label	Product Code
16G	80mm	•	Closed End 3 Eyes	•	100/394/116
18G	80mm	•	Closed End 3 Eyes	•	100/394/118

Supplied in packs of 10



Specification

Patient Preparation														Procedure Components						
Tuohy Needle	Sterile Field	Hand Towels x 2	Fenestrated Drape	Gauze Swabs x 5	Applicator Sponges x 2	Solution Prep Wells x 2	Filter Kwill	3ml Luer Slip Syringe	20ml Luer Slip Syringe	25G x 5/8" Hypodermic Needle	22G x 5/8" Hypodermic Needle	18G x 5/8" Hypodermic Needle	16G x 5/8" Trocar	Tuohy Needle (Blade 80mm) With Attachable Wings	LORD	Clear Catheter & Connector	Catheter Identification Label	0.2µm Epidural Filter	Catheter Fixation Sponge	Product Code
16G	•	•	•	•	•	•	•	•	•	•	•	•	•	16G •	10ml Plastic	Closed End 3 Eyes	•	•	•	100/390/116
17G	•		•	•	•			•	•	•		•		17G •	10ml Glass L/L	Open End		•		E622
17G	•		•	•	•			•	•	•		•		17G •	10ml Plastic	Open End		•		G455
18G	•	•	•	•	•	•	•	•	•	•	•	•	•	18G •	10ml Plastic	Closed End 3 Eyes	•	•	•	100/390/118
18G	•		•	•	•			•	•	•		•		18G •	10ml Glass L/L	Open End		•		G745
18G	•		•	•	•			•	•	•		•		18G •	10ml Glass L/L	Closed End 3 Eyes		•		G895
18G	•		•	•	•			•	•	•		•		18G •	10ml Plastic	Closed End 3 Eyes		•		L794
17G Single Shot	•		•	•	•		•	•	•	•		•		17G •	10ml Glass L/L					E621

Maxipacks supplied in packs of 10

Epidural Maxipacks

A convenient, single-use procedure pack offered in a logical two-layer format with the upper tray containing a selection of patient preparation components and the lower tray containing all the essential epidural procedure components. Available in 16G, 17G and 18G.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139

Supplied in packs of 10 x 100

Spinal Anaesthesia

Complementing the epidural systems products, Smiths Medical applies the same meticulous attention to detail and quality to a range of precision-engineered spinal needles. Included in the spinal needle range is the RapID® brand of needles. Designed to provide maximum performance without compromising safety, the RapID® spinal needle selection delivers the high performance demanded by today's healthcare professionals. Spinal needles are available in Lancet (Quincke), Atraumatic and Pencil (Whitacre) tip designs, and offered as either individual needles supplied with a matched introducer needle or in convenient procedure trays.

Recognising that procedural techniques vary, the RapID® range of spinal needles are also available through the SELECT custom kitting service, allowing clinicians to customise a spinal procedure tray to suit individual needs.

Supporting the spinal needle range is the 28g Spinal Micro-catheter System designed to facilitate effective regional anaesthesia through continuous intrathecal administration.

smiths

Pencil Point Spinal Needle Sets (Whitacre)

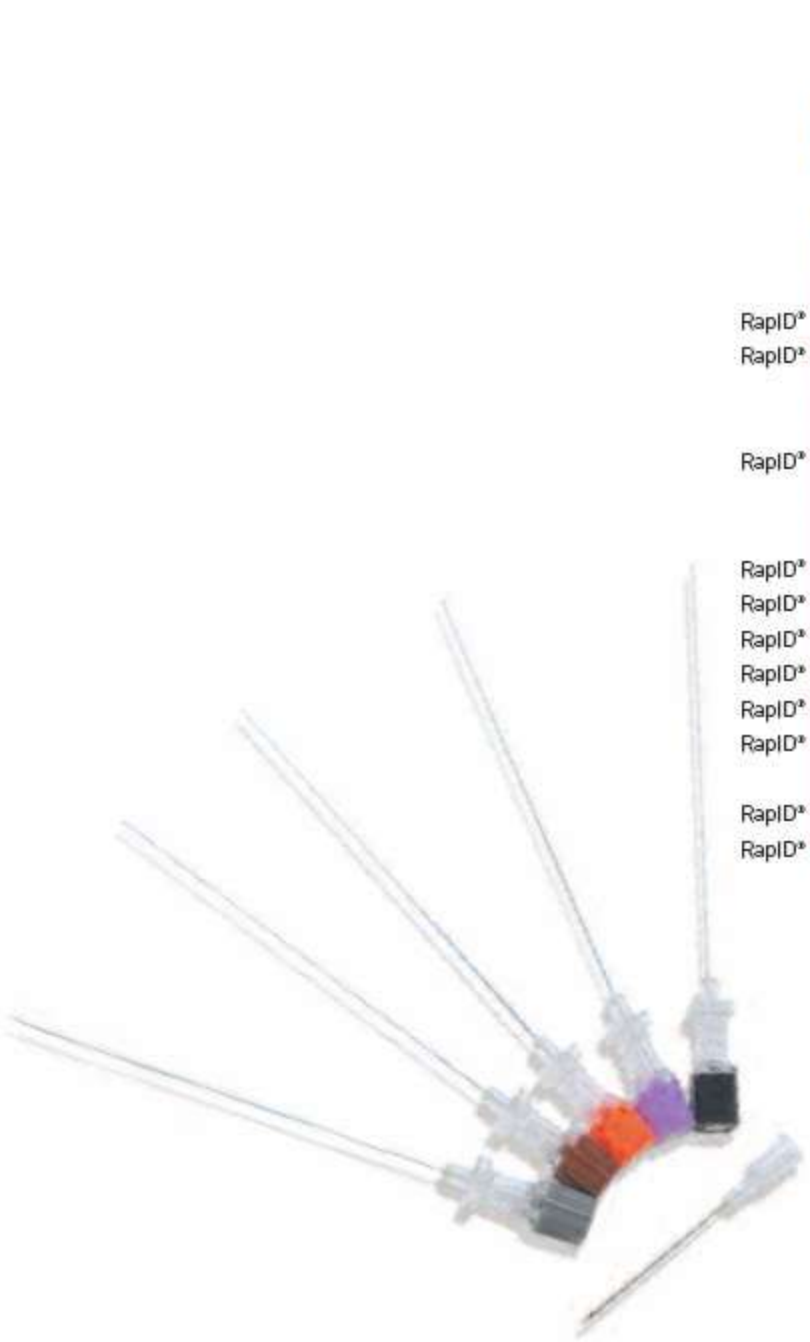
Specification

	Spinal Needle	Length	Introducer Needle	Product Code
RapID®	22G	90mm	18G	100/496/122
RapID®	24G	90mm	20G	100/496/124
	24G	90mm		L742**
	24G	90mm	20G	M121*
RapID®	25G	90mm	20G	100/496/125
	25G	90mm		L741**
	25G	90mm	20G	M122*
RapID®	25G	115mm		100/493/815
RapID®	25G	115mm	20G	100/492/815
RapID®	26G	90mm	20G	100/496/126
RapID®	26G	115mm		100/493/816
RapID®	26G	115mm	20G	100/492/816
RapID®	27G	90mm	20G	100/496/127
	27G	90mm	22G	M729*
RapID®	27G	115mm	20G	100/492/817
RapID®	27G	115mm		100/493/817

Supplied in packs of 20

**Supplied in packs of 50

*Supplied in packs of 60



RapID® Spinal Needle Sets and Midi-Trays

The RapID® range of Spinal Needles is available either as a needle set or in a Midi-Tray format.

The Midi-Tray provides a systematic presentation of the key components necessary for the administration of single-shot Spinal Anaesthesia.

- Available in both Pencil and Lancet tip variants from 22G through to 29G depending on patient and procedural requirements. Extra length needles available in 25G, 26G and 27G.
- Pencil tip needles incorporate precision-engineered tip and eye geometry for atraumatic insertion and reduction in Post Dural Puncture Headache (PDPH).

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139

Supplied in packs of 10 x 100

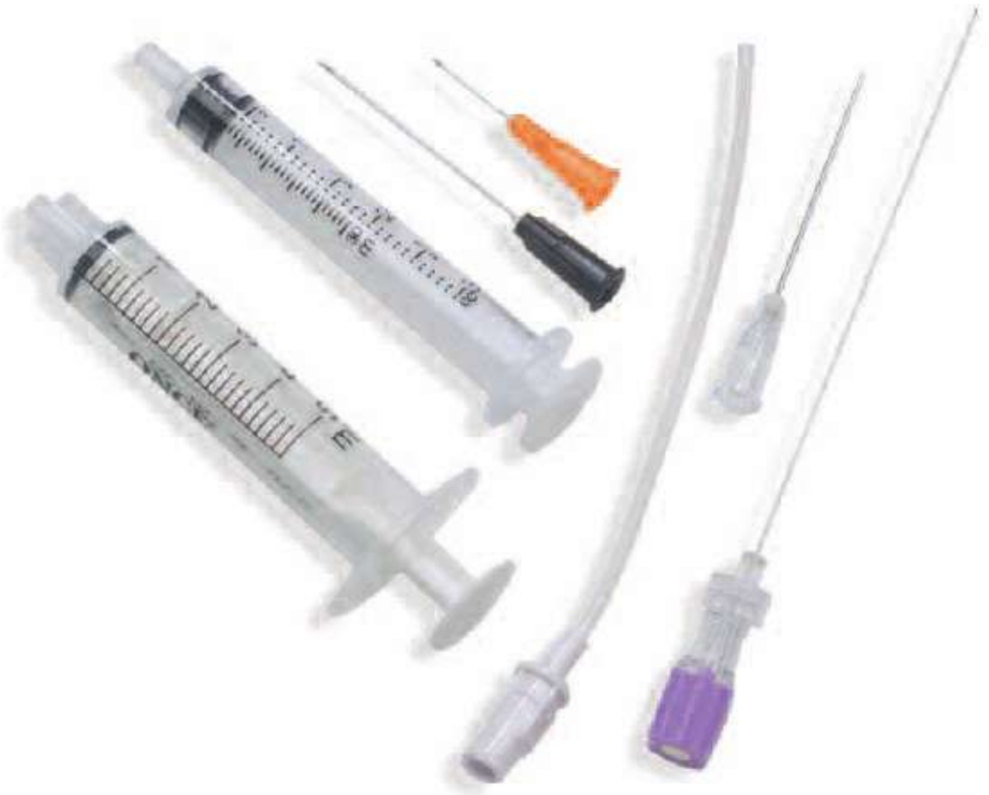
Lancet Point Spinal Needle Sets (Quincke)

Specification

	Spinal Needle	Length	Introducer	Product Code
RapID*	22G	90mm	18G	100/496/022
	22G	90mm		L746**
RapID*	24G	90mm	20G	100/496/024
RapID*	25G	90mm	20G	100/496/025
	25G	90mm	20G	M118*
RapID*	26G	90mm	20G	100/496/026
	26G	90mm	20G	M119*
RapID*	27G	90mm	20G	100/496/027
	27G	90mm		L743**
	27G	90mm	22G	M120*
	29G	90mm	22G	M341*

Supplied in packs of 20
**Supplied in packs of 50
*Supplied in packs of 60

- Size and positioning of the lateral eye minimises the potential for 'transdural positioning'. This ensures accurate delivery in the subarachnoid space.
- Clear hubs and excellent cerebrospinal fluid flashback performance provides rapid identification of correct needle placement.
- Colour-coded stylets allow easy identification of needle size.
- Supplied with a matched introducer needle to ensure accurate and safe needle placement within the subarachnoid space.



Specification

Spinal Needle	Length	Introducer Needle	Intradermal Needle	Hypodermic Needle	Syringe	Filter Kwill	Product Code
22G	90mm	18G	25G	22G	3ml & 5ml	•	100/497/122
25G	90mm	20G	25G	22G	3ml & 5ml	•	100/497/125
26G	90mm	20G	25G	22G	3ml & 5ml	•	100/497/126
27G	90mm	20G	25G	22G	3ml & 5ml	•	100/497/127

Supplied in packs of 10

Midi-trays

Midi trays are available in pencil point format, containing a spinal needle and introducer, supported by the key components necessary for administration of the local anaesthetic prior to needle insertion.

Filter kwill (5µm, priming volume of 0.3ml) removes particulate matter when drawing up, maximising patient safety.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139

Supplied in packs of 10 x 100

Patient Preparation												Procedure Components						
Spinal Needle Gauge	Sterile Field	Hand Towels x 2	Fenestrated Drape	Gauze Swabs x 5	Applicator Sponges x 2	Solution Prep Wells x 2	Filter Kwill	3ml Luer-Slip Syringe	22G x 11/2" Hypodermic Needle	25G x 5/8" Hypodermic Needle	16G x 5/8" Trocar	Spinal Needle Gauge	Spinal Needle Type - P=Pencil, L=Lancet, A=Atraumatic	Spinal Needle Brand R=Rapid, A=Abbott, BD	6ml Luer Lock Syringe	5ml Plastic Syringe	Introducer Needle	Product Code
22G	•	•	•	•	•	•	•	•	•	•	•	22G	P	R	•		18G	100/389/822
22G	•	•	•	•	•	•	•	•	•	•	•	22G	L	R	•		18G	100/389/022
22G	•		•	•	•		•	•				22G	L	BD		•	18G	E619
24G	•		•	•	•		•	•				24G	A	A		•	19G	G888
25G	•	•	•	•	•	•	•	•	•	•	•	25G	P	R	•		18G	100/389/825
25G	•	•	•	•	•	•	•	•	•	•	•	25G	L	R	•		18G	100/389/025
25G	•		•	•	•		•	•				25G	P	A		•	19G	G973
25G	•		•	•	•		•	•				25G	L	BD		•	19G	E620
26G	•	•	•	•	•	•	•	•	•	•	•	26G	P	R	•		18G	100/389/826
26G	•	•	•	•	•	•	•	•	•	•	•	26G	L	R	•		18G	100/389/026
26G	•		•	•	•		•	•				26G	L	BD		•	20G	G421
27G	•	•	•	•	•	•	•	•	•	•	•	27G	P	R	•			100/389/827
27G	•	•	•	•	•	•	•	•	•	•	•	27G	L	R	•			100/389/027
27G	•		•	•	•		•	•				27G	L	BD		•	20G	G972

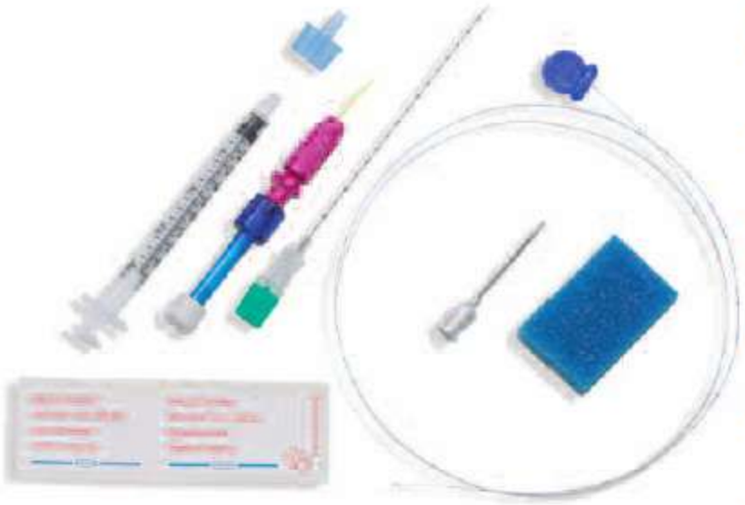
All Spinal Maxipacks supplied in packs of 10

Spinal Maxipack, Pencil Point Needle & Lancet Tip Needle

The spinal Maxipack provides all the essential components required for spinal anaesthesia in a single pack.

Presented in a logical two-layer format, the upper tray contains a selection of patient preparation components and the lower tray contains the essential components to perform the spinal block.

Available in 22G to 27G pencil tip or lancet tip format, dependent on the patient and procedure requirements, high performance and safety are assured.



The System Includes

- 23G Crawford Spinal Needle with optimised 30° angle of bevel.
- Needle bevel heel and sides blunted to minimise risk of potential catheter shearing.
- 28G Styletted Microcatheter.
- Graduated markings permit accurate catheter positioning.
- PTFE coated stylet aids easy withdrawal from catheter.
- Correct catheter placement may be confirmed by aspiration of CSF.
- Supplied with catheter identification label to avoid confusion with epidural catheters or other infusion lines.
- Supplied with Luer lock connector.
- 1ml syringe for accurate dose delivery.
- Compact 0.2µm syringe filter .

Specification
Spinal Microcatheter Kit

Pack Contents	Product Code
23G Crawford Spinal Needle	100/384/023
28G Styletted Microcatheter	
18G Introducer Needle	
1ml Syringe	
Microcatheter Fixation Device	
Luer Lock Connector	
Microcatheter Guide	
Spinal Catheter Label	
0.2µm Syringe Filter	

Supplied in packs of 2

Single Packed Filter

0.2µm Syringe Filter	100/385/020

Supplied in packs of 10

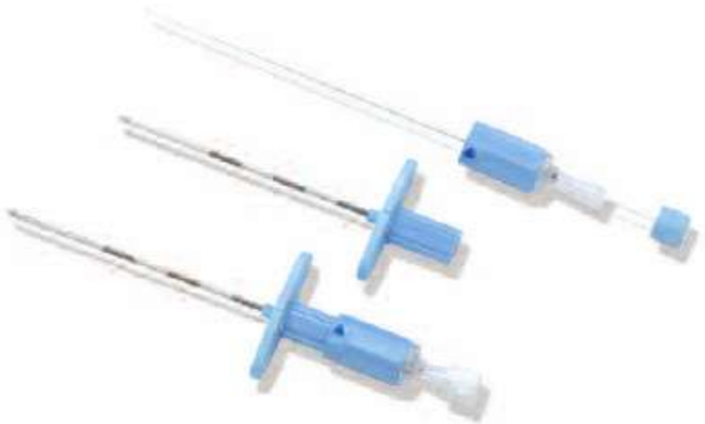
Microcatheter System

The Spinal Microcatheter System for continuous spinal anaesthesia is considered appropriate for a wide range of surgical and pain management applications, providing a rapid and controlled response. The technique permits precise dose titration and allows minimal amounts of local anaesthetic to be used, minimising the risk of systemic toxic reactions.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139

Supplied in packs of 10 x 100



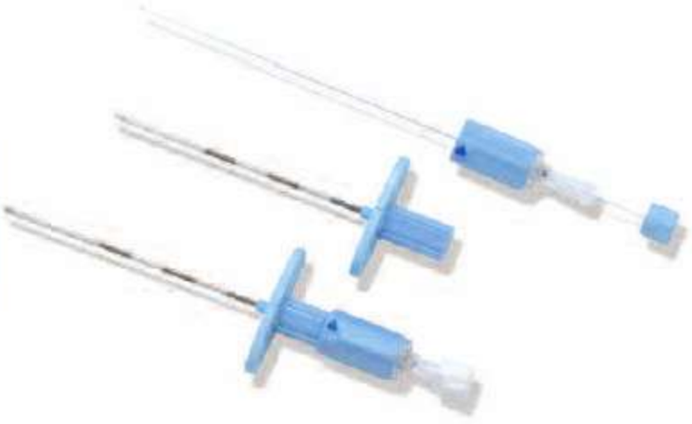
Combined Spinal Epidural Systems

Bringing together the well documented advantages of epidural and spinal anaesthesia, the Smiths Medical range of Combined Spinal Epidural products includes the unique CSEcure® locking needle system.

Launched in 1998, the CSEcure® needle system provides a safe and effective solution to needle control during the CSE procedure, without compromising the all-important feel. CSEcure® is available in a wide range of pack options from individual sets of needles through to full procedure packs.

Recognising that procedural techniques vary, the CSE needle range is also available through the SELECT custom kitting service, allowing the clinician to customise a CSE procedure tray to suit their individual needs. In addition, the CSE range offers a selection of traditional non-locking needle systems supplied as either matched needle sets or in full procedure trays. Now offered in the traditional 'needle-through-needle' CSE range is a back-eye design of Tuohy needle to facilitate spinal needle placement.

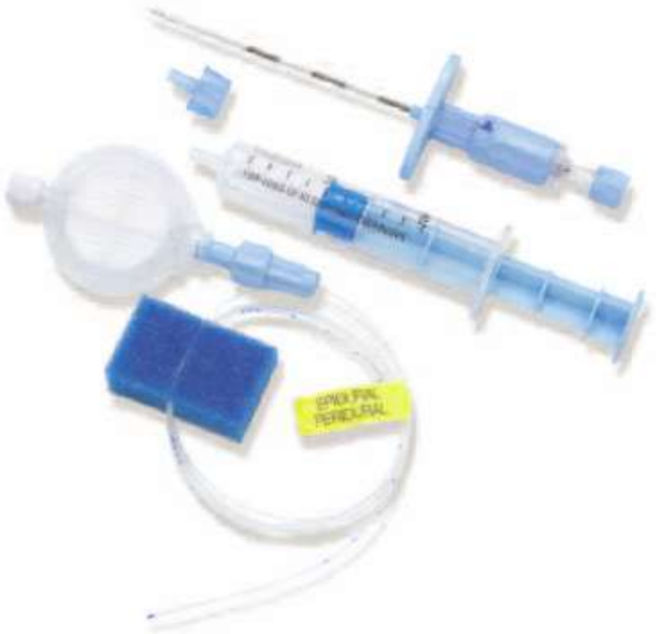
Needle Sets



Specification
CSEcure® Needle Sets

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Needle Type	CSEcure® Lock	Product Code
16G	•	26G	Pencil	•	100/396/916
16G	•	27G	Pencil	•	100/396/716
18G	•	27G	Pencil	•	100/396/718

Needle Sets supplied in packs of 10



Specification
CSEcure® Minipacks

(contains CSEcure® needle set with lock, catheter (3 eyes) and connector, Filter (0.2µm), LORD, Fixation sponge, catheter ID label)

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Need Type	Product Code
18G	•	27G	Lancet	100/491/318
16G	•	26G	Pencil	100/491/916
16G	•	27G	Pencil	100/491/716
18G	•	27G	Pencil	100/491/718

Portex CSE Minipacks supplied in packs of 10

CSE Needle Systems

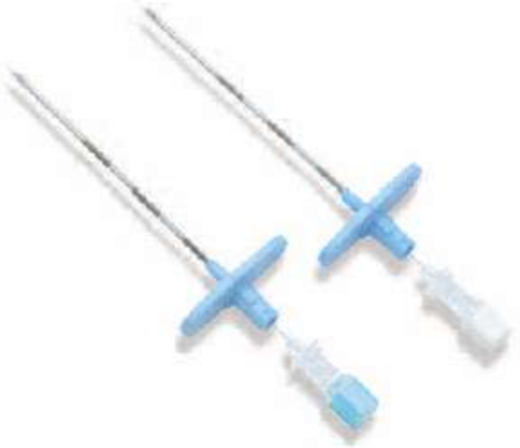
- Providing the rapid onset and reliability of a spinal block, allowing anaesthesia to be prolonged both intra and post-operatively via an epidural catheter.
- Designed for optimal performance, minimising drag of needle through needle and maximising feel of dural puncture.
- Rapid CSF flashback to confirm correct needle tip position.
- CSEcure's® unique needle hub locking feature enables tip relationships to be maintained after dural puncture, providing increased confidence of correct spinal needle tip position during injection of the anaesthetic.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139

Supplied in packs of 10 x 100

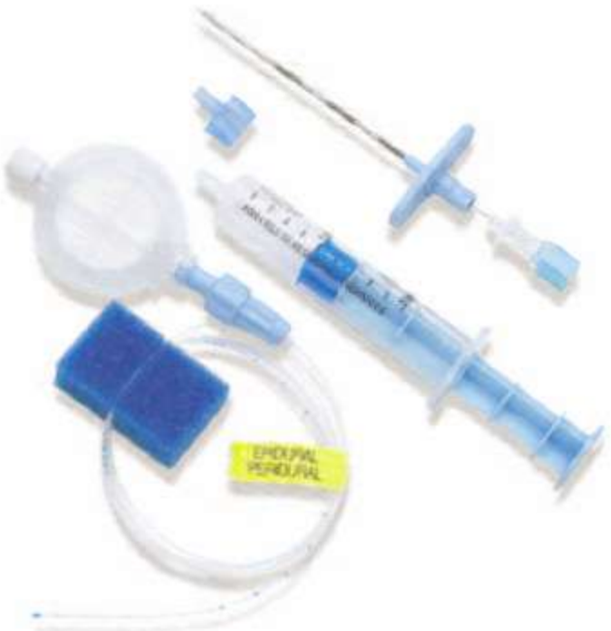
Traditional (non-locking) Needle Sets



Specification
Traditional (non-locking) Needle Sets

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Needle Type	Back Eye	Product Code
18G		25G	Pencil	•	M145*
16G	•	26G	Lancet		100/396/116
16G	•	26G	Pencil		100/396/816
16G	•	27G	Pencil		100/396/616
18G	•	27G	Pencil		100/396/618

Supplied in packs of 10
*Supplied in packs of 20



Specification
Traditional (non-locking) CSE Minipacks

(contains CSE needle set, catheter (3 eyes) and connector, Filter (0.2µm), LORD, Fixation sponge, catheter ID label)

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Needle Type	Product Code
18G		25G	Pencil	M146*
16G	•	26G	Lancet	100/491/116
18G	•	26G	Lancet	100/491/118
18G	•	27G	Pencil	100/491/618
16G	•	26G	Pencil	100/491/816
18G	•	26G	Pencil	100/491/818

Supplied in packs of 10
*Supplied in packs of 20 (back eye needle, no catheter label, no fixation sponge)

- Maximum of 15mm spinal needle tip protrusion from Tuohy needle.
- In locked position the spinal needle is free to rotate, enabling 360° freedom for drug dispersal in preferred direction.
- Pencil point needles provide a satisfactory solution to the problem of Post Dural Puncture Headache and atraumatic entry into the subarachnoid space.
- Excellent drug distribution is achieved through three helically-located lateral eyes within the clear catheter, minimising the potential for the localised pooling of drug solutions within the epidural space.

Plexus Anaesthesia

Supporting the growing interest in Plexus Anaesthesia for Pain Management, Smiths Medical's Plexus Anaesthesia Systems offer the Anaesthetist a more targeted approach to Pain Management.

The TRACER® III nerve stimulator is a light-weight portable system, allowing easy confirmation of needle placement to target nerves for procedures where a motor response can be elicited. The small micro current delivered by the TRACER® III stimulates the larger A Alfa motor fibres before the smaller A Delta or C fibres responsible for pain, thereby achieving a motor response without eliciting pain.

TRACER® III automatically compensates for patient resistance and displays the actual current being delivered at the tip of the needle. As well as current intensity, the easy-to-read screen displays the maximum current range, pulse frequency, the pulse width and current battery life status.

TRACER® III

Ref Code	NL3
Dimensions	2.9" (7.3cm) x 5.5" (14.0cm) x 1.4" (3.4cm)
Weight	9.6 oz (275g) with 9v battery
Output Current	0.05-5.0mA ± 1% (into a load of 12 kOhms or less)
Pulse Frequency	Programmable 1 Hz/2Hz ±2%
Pulse Width	50, 100, 300, 500, 1000 microseconds ± 10%
Pulse Risetime	Less than 5 microseconds open circuit
Power	One 9v Alkaline Battery
Regulatory	CE marked to MDD EC93/42, UL 2601-1, CSA 22.2 no.601.1

SoloStim® Foot Control

Product Code	NLP3
Dimensions	8" (20.3cm) x 3.75" (9.4cm) x 2.75" (7.0cm)
Weight	2.1 lbs (0.96kg)

TRACER® III Protective Case

Product Code	NLB3

TRACER® III Replacement Leadset

Product Code	NLC3

TRACER® III Adaptor Lead

Product Code	NLA3

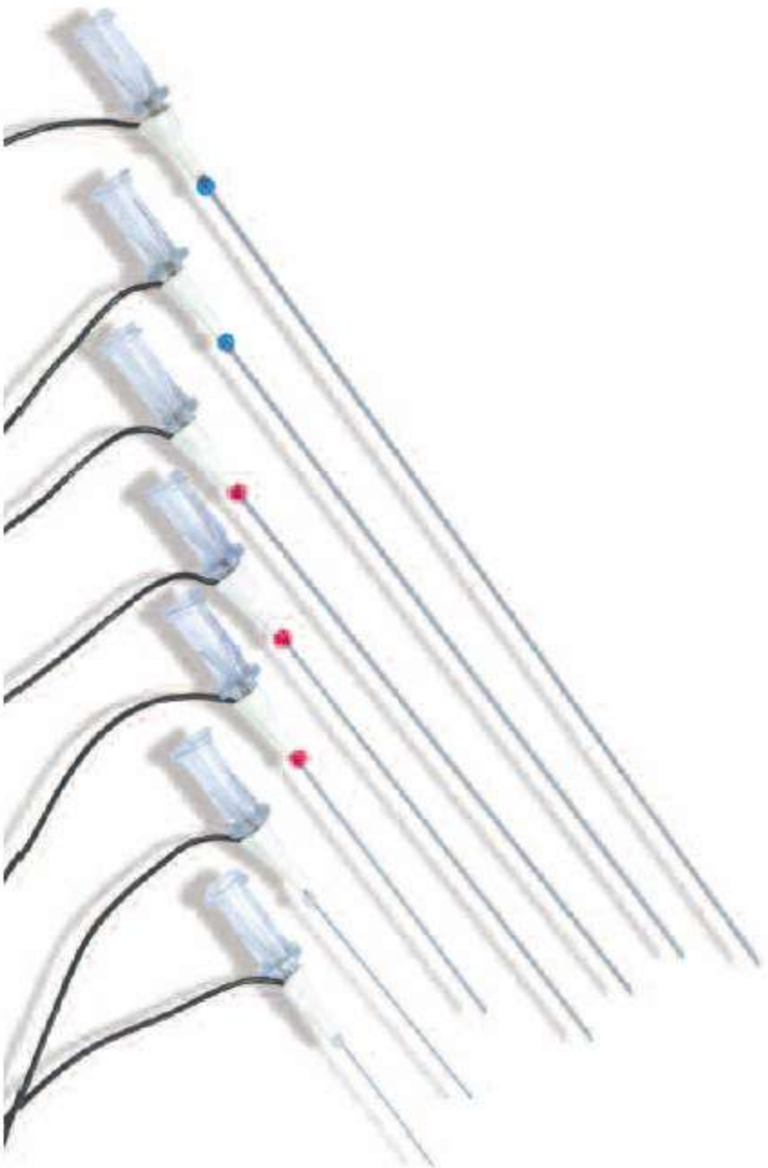
Plexus Anaesthesia

TRACER III® also features:

- Volume control with audible tone changes.
- Audio open-circuit alarm.
- Automatic shut-off after 20 minutes of non use to preserve battery life.
- Two pulse frequency options 1Hz and 2Hz.
- Five pulse width settings 0.05, 0.1, 0.3, 0.5, and 1.0 msec.

Unique to Smiths Medical's Plexus Anaesthesia System is the SOLOSTIM™ foot control. Used in conjunction with the TRACER III® Nerve Stimulator, it allows hands-free operation and control of the stimulating current, enabling the clinician to use both hands for accurate needle placement and nerve location.

- Two operating ranges can be selected. 0.05-5.0 mA and 0.05-1.5mA.



Single Shot Needles

Needle Gauge	Needle Length	Product Code
25	25mm	25/025/PB
25	40mm	25/040/PB
22	50mm	22/050/PB
22	80mm	22/080/PB
20	100mm	20/100/PB
20	120mm	20/120/PB
20	150mm	20/150/PB

Bevel: 30° B Block
Insulation: >50 kOhms resistance
Hub: Transparent female Luer fitting
Lead Wire: 18" long with 1.5mm touch proof connector

CONTINUOUS PROLONG™ Sets

Needle Gauge	Needle Length	Product Code	Tuohy style needle	Continuous Block Catheter
19	40mm	19/040/PL		yes
19	50mm	19/050/PL		yes
19	100mm	19/100/PL		yes
19	150mm	19/150/PL		yes
18	40mm	18/040/PLT	•	yes
18	50mm	18/050/PLT	•	yes
18	100mm	18/100/PLT	•	yes
18	150mm	18/150/PLT	•	yes

(supplied with 21G catheter)
Bevel:
30° B Block for 19 gauge
tuohy tip for 18 gauge
Insulation: >50 kOhms resistance
Hub: Transparent female Luer fitting
Lead Wire: 18" long with 1.5mm touch proof connector
Catheter: 21G closed end 3 lateral eyes Radio opaque

A full range of insulated needles and catheter sets support the TRACER III® and SOLOSTIM™ System. Ranging from short needles suitable for upper extremity blocks, the needles incorporate an advanced Hydro-Slick teflon coating which is laser-stripped at the tip to ensure a high degree of insulation and accuracy.

Epidural and Intra-Spinal Ports & Access Systems

Recognising the need for effective Chronic Pain Management, the PORT-A-CATH® brand of implantable Epidural and Intra-spinal Ports from Smiths Medical, provide an effective and reliable means of administering Pain Management Therapies over extended periods of time. Setting standards in excellence and innovation, the Deltec PORT-A-CATH® brand of Epidural and Intra-spinal Ports offer unsurpassed performance and reliability.

Smiths Medical also provides a comprehensive range of Vascular Access Ports for Intravenous and Intra-arterial Therapies. Please see our Vascular Access Catalogue for more details.

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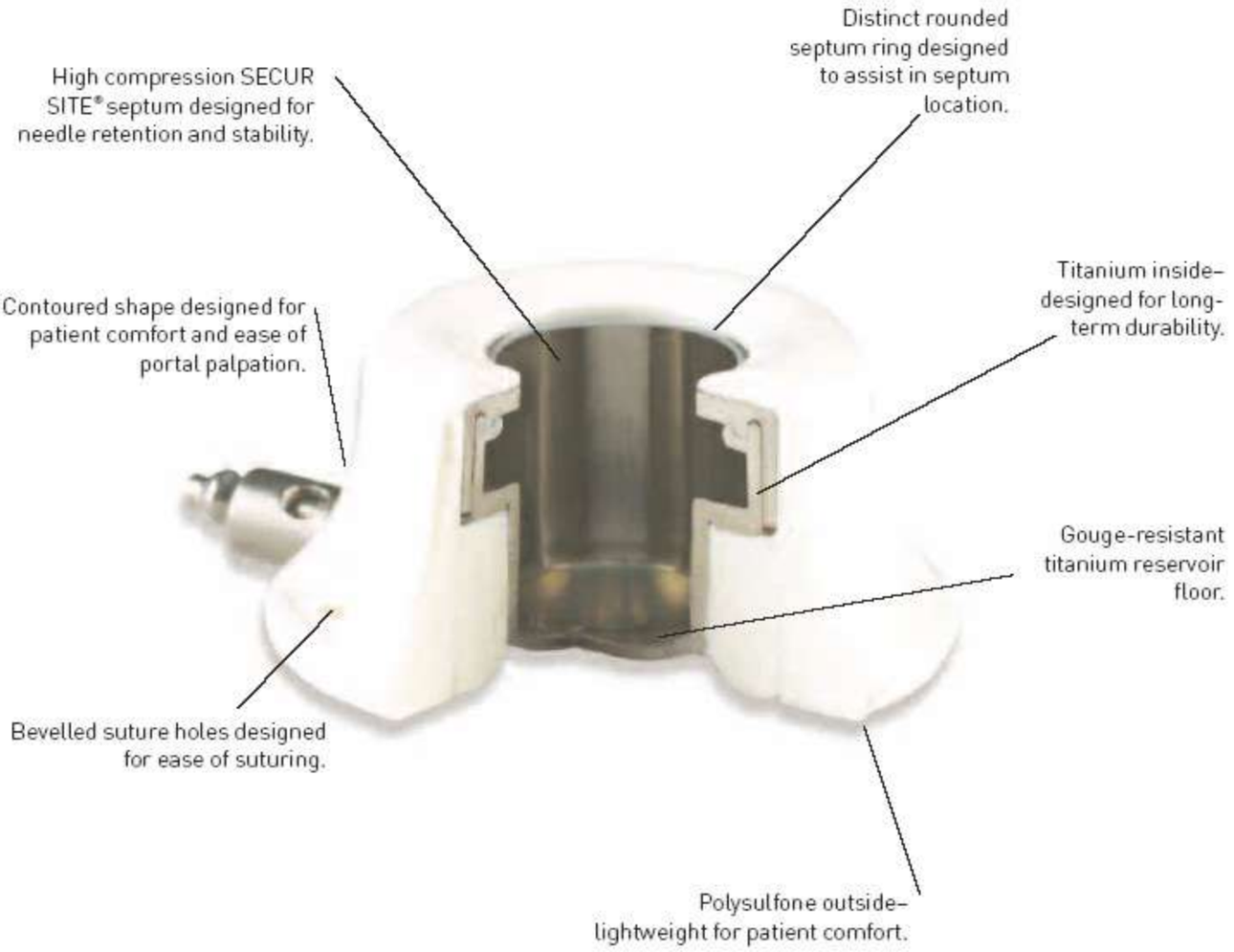
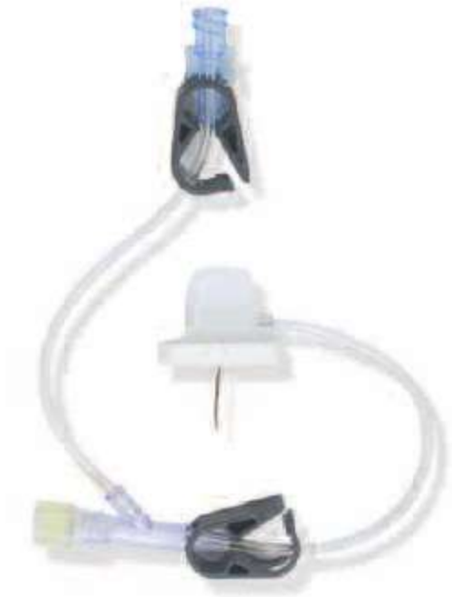


Specification

	Catheter material	OD (mm)	ID (mm)	Length (cm)	Product Code
Epidural Port	Polyurethane Open ended	1.2	0.5	91	21-1501-24
Spinal Port	Polyurethane Closed end with side hole	0.9	0.5	91	21-1500-24

Manufactured from a lightweight polysulfone body incorporating a gouge-resistant titanium base, PORT-A-CATH® II is designed for long-term durability and patient comfort. The compressed silicone septum provides secure needle retention when accessing the port, allowing up to 2000 needle punctures. All ports are supplied with a polyurethane catheter in a full procedure tray.

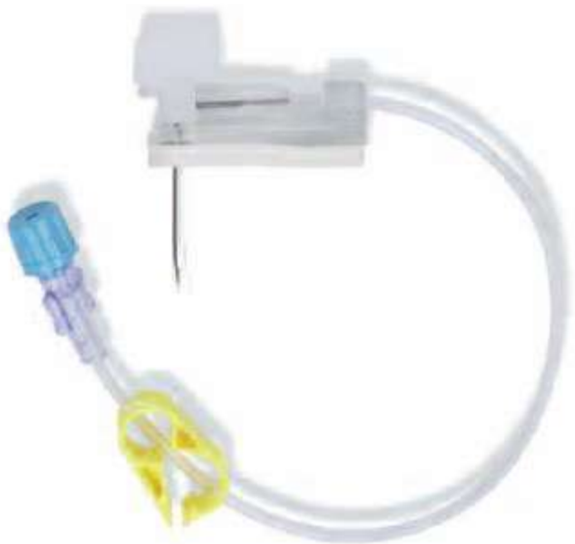


Gripper® Needles

Specification

Gauge	Length (mm)	Product code with Y-site	Product code without Y-site
22G	19	21-2939-24	21-2733-24
22G	25	21-2940-24	21-2714-24
22G	32	21-2941-24	21-2715-24
20G	19	21-2947-24	21-2734-24
20G	25	21-2948-24	21-2717-24
20G	32	21-2949-24	21-2718-24
19G	19	21-2955-24	21-2735-24
19G	25	21-2956-24	21-2720-24
19G	32	21-2957-24	21-2721-24
20G	16	21-2746-24	21-2736-24
22G	16	21-2738-24	21-2737-24

Supplied in packs of 12



Gripper® Plus Safety Needles

Specification

Gauge	Length (mm)	Product code with Y-site	Product code without Y-site
19G	19	21-2868	21-2768
19G	25	21-2869	21-2764
19G	32	21-2870	21-2765
20G	16	21-2864	21-2769
20G	19	21-2865	21-2767
20G	25	21-2866	21-2762
20G	32	21-2867	21-2763
22G	16	21-2860	21-2770
22G	19	21-2861	21-2766
22G	25	21-2862	21-2760
22G	32	21-2863	21-2761

Supplied in packs of 12

Supporting the Epidural and Intra-spinal Ports is the GRIPPER® and GRIPPER® PLUS range of non-coring Huber needles for accessing ports. The removable contoured grip provides confident needle placement, while the low profile design eliminates the need for bulky dressings. When in situ, the cushioned needle platform stabilises the needle and increases patient comfort. The new GRIPPER® PLUS needle offers access to the port in one easy and safe motion. Featuring an effective needle stick protection system, GRIPPER® PLUS provides improved clinical safety when removing the needle from the port.

All GRIPPER® and GRIPPER® PLUS access needles have integrated extension lines featuring needle-less Y-site access, and secure Luer lock connectors allowing connection to an appropriate infusion pump if required.

- A wide variety of gauges and lengths to accommodate most ports.
- Colour-coded C-clamp for ease of needle gauge identification.

With over 400,000 implantations during the last 10 years the Smiths Medical range of ports and needles gives you and your patients the confidence and security you deserve.

smiths

Select Custom Kit Service

Smiths Medical recognises that health professionals are as individual as their patients. The Select Custom Kitting service allows clinicians the opportunity to customise their own kits to suit their personal component preferences and operational needs. The service offers the following benefits to both users and purchasers:

- With a simple ordering system, custom kits ensure you receive exactly the right components for each individual, with no extras to assemble and nothing wasted.
- Considerable time-saving gained from set-up to procedural application as all the items are present in one package.
- Risk of infection is reduced as all items are only handled once.
- Stockholding is reduced as packs can be held by your local distributor according to forecast and demand.

The Select Custom Kit process

It is quick and easy to create and produce any kit to suit your exact requirements.

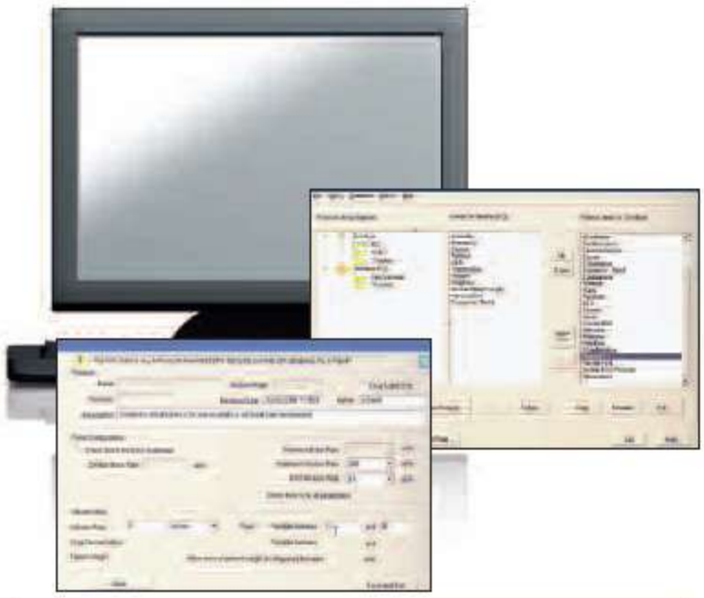
1. Select kit components with our Product Specialist.
2. Our Custom Kit Unit prepares sample(s) for approval in 3 days.
3. Sample(s) approved and order placed.
4. Our Custom Kit Unit produces initial stock.
5. Usage forecast agreed and 2-3 months stock produced to be held by distributor.
6. Standing order placed by hospital with distributor with extra supplies available for call-off at all times.

Pumps

OMNIFUSE® PCA

Designed with safety in mind, OMNIFUSE® PCA breaks new ground in syringe pump design. Specifically developed for Patient Controlled Analgesia (PCA), OMNIFUSE® PCA meets the needs of today's demanding Pain Management Therapies.

The intuitive point and select user interface, combined with a wide range of features which can be enabled or disabled, provides a high degree of operational flexibility and the desired balance between simplicity and sophistication.



Specification

Dose Range	0.1ng – 99.9mg
Dose Duration	1 second – 15 minutes
Clinician Override Dose Range	0.1ng – 99.9mg
Loading Dose Range	0.1ng – 99.9mg
Background (Dose) Rate Range	0.1ng/h – 500mg/h
Background Rate Range (with boluses)	0.1 – 20ml/h
Background Rate Range (no boluses)	0.1 – 800ml/h
Bolus Rate Range	0.1 – 800ml/h
Bolus Rate Range (timed)	1 second – 15minutes
Dose Limit Range by Mass	1ng – 9999mg
Dose Limit Range by Volume	1 – 9999ml
Dose Limit Range by Demands	1ng – 50 demands
Dose Limit Period	1 – 8 hours or variable
Accuracy	Volumetric: ± 2% Linear: ± 0.25% using the Braun Omnifix 50ml syringe
Syringe Sizes	2ml – 60ml
Purge Rate	0 – 800ml/h
KVO Rate	0 – 2ml/h

Occlusion Pressure Alarm Limits	5 levels between 180 and 1250mmHg
History	3000 events
Battery Type	Sealed Lead Acid
Battery Life	10 hours (@ 5ml/h)
Battery charge time	10 hours to full charge
AC Power Supply	100 – 240V at 50/60Hz 50W
Weight	3.5kg (not including pole clamp)
Dimension	384 x 170 x 92mm (not including locking pole clamp)
Fluid Ingress Protection	IPX4
Electrical Safety	Class 1, Type CF
Design Standards	EN 60601-1, EN 60601-2 EN 60601-4, EN 60601-2-24

Part numbers

Omnifuse® PCA 0153-0001 (this part number refers to the UK variant).
Omnifuse® Drug Protocol Management System 0153-0084.

- Supplied with Drug Protocol Software as standard to help minimise Medication Errors during programming.
- Large display screen can illustrate the current infusion profile in a graphical format.
- Infusion history which can be viewed over 1 hour periods.
- Displays showing graphical representations of patient profiles when pain, nausea and sedation parameters are entered into the pump.
- Electronic Patient Handset illuminates when a bolus is available.
- The 'ASLEEP' function allows the pump to be programmed and left in a dormant state awaiting use.

Confidence and safety when connecting the patient to OMNIFUSE® PCA can be achieved using the FLO-SAFER™ range of extension sets designed to suit every individual patient requirement.

FLO-SAFER™ Extension Set System

- Include line clamps with an option of an integral Anti-Syphon Valve.
- Available with a fluid path of PVC or PE medical grade plastics.
- Yellow extension sets that are colour-coded to conform with the internationally recognised colour for epidural use.
- Wastage and consequent drug expenditure reduced by low volume sets that incorporate narrow-bore tubing, reducing priming volume by 75%.
- Integral Roberts Clamp giving the confidence of a safer and convenient method of flow control.

Specification
PVC Extension Sets & R Clamp

Length (cm)	Priming	Product Code
50	0.5ml	0128-0196
100	1.0ml	0128-0197
150	1.5ml	0128-0122
200	2.0ml	0128-0198

Sets supplied in packs of 50

Specification
PVC Extension Sets & ASV & R Clamp

Length (cm)	Priming	Product Code
50	0.5ml	0128-0251
100	1.0ml	0128-0252
150	1.5ml	0128-0253
200	2.0ml	0128-0254

Sets supplied in packs of 50

Specification
PE Lined Extension Sets & ASV & R Clamp

Length (cm)	Priming	Product Code
50	0.5ml	0128-0255
100	1.0ml	0128-0256
150	1.5ml	0128-0257
200	2.0ml	0128-0258

Sets supplied in packs of 50

Specification
PE Lined Extension Sets (narrowbore 0.5mm) + ASV + R Clamp

Length (cm)	Priming	Product Code
100	0.25ml	0128-0259
150	0.4ml	0128-0260

Sets supplied in packs of 50

Specification
Yellow Epidural PU Extension Sets + ASV + R Clamp

Length (cm)	Priming	Product Code
150	1.5ml	0128-0261
200	2.0ml	0128-0262

Sets supplied in packs of 50

Specification
Yellow Epidural PU Extension Sets + S Clip

Length (cm)	Priming	Product Code
150	1.5ml	0128-0263
200	2.0ml	0128-0264

Sets supplied in packs of 50

Specification
150cm PVC Extension Sets + Y Set + ASV + Non-Return Valve and Loop

	Product Code
Primary Line - 1.5ml / **Secondary Line** - 2.0ml	0128-0121

Sets supplied in packs of 50

Specification
150cm PVC Extension Sets + Pressure Sensing Disc

Priming	Product Code
2.2ml	0130-0041

Sets supplied in packs of 50

ASV – Anti-Syphon Valve
PVC – Polyvinylchloride
PE – Polyethylene
PU – Polyurethane
R Clamp – Roberts Clamp
S Clip – Slip Clip

CADD-Legacy® PCA

CADD Legacy® PCA is safe, reliable and durable.

Specifically dedicated to PCA applications, the CADD Legacy® PCA pump is particularly suited for Pain Management Therapies via the intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural and intrathecal routes.

CADD Legacy® PCA is capable of continuous, demand dose and clinician bolus infusions that can be used independently or in combination with each other.

- Enhanced keypad and message display screen, providing easy-to-read information for programming adjustments and troubleshooting.
- Built-in safety features allowing you and your patient to be alerted to any undesirable events in the pump's operation.
- Air-in-line detector indicating the presence of air administration set tubing and the upstream and downstream occlusion sensors detecting any interruptions of fluid delivery.

Specification

Product Code	**21-6300-51**
Delivery Modes	Continuous, Demand Dose, Clinician Bolus (modes can be used independently or in combination).
Indications	Pain management infusion therapies.
Delivery routes	Intravenous, Intra-arterial, Subcutaneous, Intraperitoneal, Epidural, Intrathecal.
Programming	
Programming Units	ml,mg,mcg
Reservoir Volume	1 ml – 9,999ml or not in use
Drug Concentration	0.1 – 100mg/ml, 1–500 mcg/ml
Continuous Rate	0 –50ml/hr, 0-5,000 mg/hr, 0 - 25,000 mcg/hr*
Dose Volume	Demand dose – 0 – 9.9ml, 0 – 990 mg, 4,950mcg, Clinical Bolus – 0–20ml, 0 – 2,000mg, 0 –10,000mcg*
Demand Dose Lockout	5 min - 24 hr
Demand Doses/hour	1 – 12
Reporting	
Reservoir Volume	0 – 9,999ml* (ml only)
Drug Concentration	
Given (volume delivered)	0 – 99,999.95ml
Doses Given	0 – 999
Doses Attempted	0 – 999

- The capacity to store the last 500 events in its memory. This information can be downloaded either directly or remotely (using a modem) to a PC or a printer using the CADD Diplomat® PC Communications System.
- Filled medication cassettes or pole-mounted fluid bags, allowing the clinician flexibility to choose medication delivery option that best suits Pain Management needs.
- Optional security shells safeguard against undesired tampering with the pump during use.
- CADD Legacy® offers a high degree of strength and durability, making it the ideal choice for ambulatory patients with an active lifestyle.

Simply Safer, The CADD-Prizm® PCS II Pain Management Pump

The CADD-Prizm® PCS II pump uses 20 years of proven ambulatory infusion system experience to provide an easy- to-use pump that optimises safety, security and pain control, whilst offering the pump information and patient reports that your Acute Pain Team needs for effective Pain Management.

Each component in the CADD Acute Pain Management System complements and supports the safe and reliable delivery of pain medication. Use of the pumps across multiple patient areas increases clinician familiarity, whether used for an ambulatory, pole-mounted, post- operative, epidural or IV infusion.

The effectiveness of delivery reaches a higher level when combined with Medication Delivery Management Software that reduces the risk of medication errors via electronic programming of the pump with standardised protocols.

- When combined with the CADD-Prizm® PCS II pump, the software will help reduce programming errors, save time and provide consistent, high quality Pain Management.
- Electronic protocol programming, archived pump and patient data and printable documentation whenever required.
- Helps reduce the risk of medication errors.
- You can quickly select and accurately program pain

General Pump Specifications*

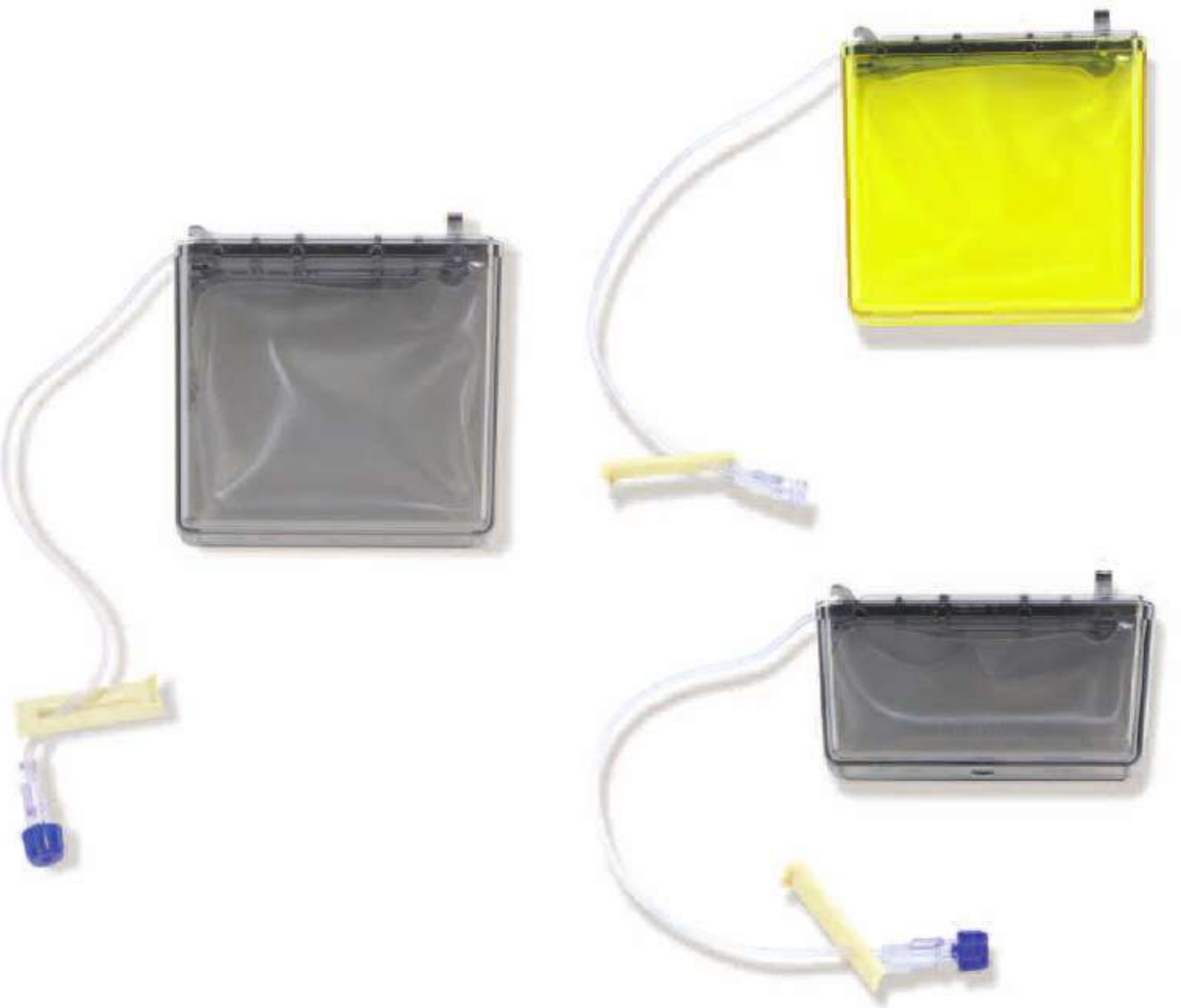
Resolution	0.050 ml per pump stroke
Size	4.4 cm x 10.4 cm x 14.1 cm (1.7 in. x 4.1 in. x 5.6 in.) excluding cassette or other accessories.
Weight	568 g (20 oz.) including 9-volt battery and empty 100 ml Medication Cassette reservoir, excluding other accessories.
Power Sources	9-volt alkaline or lithium battery such as DURACELL® Alkaline MN 1604 or ULTRALIFE® Lithium U9VL; AC adaptor.
Upstream Occlusion Sensor	Fluid is not flowing from the reservoir to the pump.
Pump Alarms	Pump has many notifications and visual/audible alarms, including low/depleted power status, low/depleted reservoir volume, cassette detached/attached, high pressure, and others related to specific pump conditions. Refer to the Operators Manual for listing of pump alarms.
Bolus Volume at Occlusion Alarm Pressure	0.050 ml resolution sets/reservoirs: ←0.25 ml
System Delivery Accuracy	±6% (nominal)
High Pressure Alarm	18 ± 9 psi
Air Detector Alarm	Single bubble greater than 0.100 ml.

PCA Delivery Mode Specifications

		Product Code
CADD-Prizm® PCS II ambulatory infusion pump Model 6101	Pump, carrying case, 50/100 ml pump pouch, pump key, remote dose cord, 9-volt battery, Operators Manual.	21-8951-51
CADD-Prizm® PCS II ambulatory infusion pump Model 6101 with yellow keypad	Pump, carrying case, 50/100 ml pump pouch, pump key, remote dose cord, 9-volt battery, Operators Manual.	21-8961-51

protocols into the CADD-Prizm® PCS II pumps, reducing the risk of manual programming errors and saving programming time.

- Use wireless technology to download to a PDA device, infusion history from the CADD-Prizm® PCS II pump and use the therapy report to help make patient management decisions. The stored information can later be archived on a PC for documentation.
- The CADD system provides three choices of medication delivery – medication cassette reservoirs, IV bags or syringes.
- The tamper-resistant housing of the medication cassette reservoir provides security and durability, while reducing the risk of contamination associated with bag spikes.
- An optional accessory, the secure and sturdy Lock Box, ensures that the pump and medication bag are locked away to prevent any tampering with the infusion. The option of colour-coded pumps, medication cassette reservoirs, administration lines and lock boxes all differentiate epidural and IV PCA delivery and enhance infusion safety.



Medication Cassette Reservoirs (must be used with Deltec Extension Set with Anti-siphon valve).

Product	Product Code	Unit
50-ml with Female Luer	21-7001-24	12/box
100-ml with Female Luer	21-7002-24	12/box
Yellow 100-ml with Female Luer	21-7100-24	12/box

Flexible Medication Reservoir

Product	Product Code	Unit
250-ml TOTM plasticised Medication Reservoir with Female Luer-activated valve	21-6167-24	48/box

CADD® Administration Sets

Product	Product Code	Unit
152 cm Tubing with Attached Bag Spike, Male Luer with Integral Anti-siphon Valve and Clamp	21-7022-24	12/box
152 cm Tubing with Attached Bag Spike, Male Luer Add-on Anti-siphon Valve and Clamp	21-7034-24	12/box
312 cm Yellow-striped with Attached Bag Spike, Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7024-24	12/box
229 cm TOTM-plasticised Tubing with Bag Spike, 0.2-micron Filter, Male Luer with Integral Anti-siphon Valve, and Clamp	21-7091-24	12/box
229 cm TOTM-plasticised Tubing with Female Luer, 0.2-micron Filter, Male Luer with Integral Anti-siphon Valve, and Clamp	21-7094-24	12/box
229 cm TOTM-plasticised Tubing with Bag Spike, In-line Anti-siphon Valve, Y-extension with One-way Female Checkvalve, Male Luer, and Clamps	21-7095-24	12/box
224 cm Yellow-striped Tubing, 0.2-micron Filter, Bag Spike, Male Luer with Integral Anti-siphon Valve and Clamp	21-7039-24	12/box

CADD® Extension Sets

Product	Product Code	Unit
76 cm with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7045-24 21-7060-24	50/box 12/box
114 cm with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7046-24 21-7061-24	50/box 12/box
152 cm with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7047-24 21-7062-24	50/box 12/box
140cm TOTM-plasticised Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve and Clamp	21-7040-24	25/box
152cm TOTM-plasticised Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve and Clamp	21-7106-24	50/box
173cm TOTM-plasticised Tubing with Male/Male Luers, In-Line Anti-siphon Valve Y-extension with One-way Female Checkvalve and Clamps	21-7092-24	12/box
229cm TOTM-plasticised Yellow-striped Tubing with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7105-24	12/box
152cm TOTM-plasticised Microbore Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve and Clamp	21-7052-24	50/box

Lock Boxes and Security Shells (for CADD-Prizm® pumps).

Product	Product Code	Unit
Security Shell Accommodates 250 medication bag, or several types of 30-ml pre-filled syringes, shell locks onto pump and may be pole-mounted using the pole-mount bracket (21-6120)	21-6117-24	each
Modified Security Shell For use with Flexible medication Reservoir (21-6127) and CADD®Administration Set with Male Luers (21-7059), Shell locks onto pump and may be pole-mounted using the pole-mount bracket (21-6120)	21-6117-24	each
Large Lockbox with Full Keypad, Air Detector Access Compatible with standard IV bags up to 500ml and pre-filled syringes up to 60ml	21-6186-51	each
Small Lockbox with Full Keypad, Air Detector Access Compatible with standard IV bags up to 100ml and pre-filled syringes up to 30ml	21-6185-51	each

Reusable Pouches

Product	Product Code	Unit
250-ml Pump Pouch Accommodates pump and up to 250-ml medication bag	21-2305-24	each
1-litre Pump Pouch Accommodates pump and 1-litre medication bag	21-2338-24	each
For CADD-Prizm® pumps		
Backpack (3-litre capacity) Accommodates CADD-Prizm® VIP pump, External Power Source (EPS) system, and up to a 3 litre, dual chamber medication bag	21-6123-24	each
Backpack (1-litre capacity) Accommodates CADD-Prizm® VIP pump, and up to a1 litre, medication bag	21-6123-24	each
For CADD-Prizm® pumps		
50-/100-ml Pump Pouch Accommodates pump with 50/100-ml Medication Cassette reservoir	21-6122-24	each
250-/500-ml Pump Pouch with shoulder strap Accommodates pump with 250/500-ml medication bag, designed to be worn on the shoulder or round the waste	21-6127-24	each
250-/500-ml Pump Pouch Accommodates pump with 250/500-ml medication bag, designed to be worn round the waste	21-6124-24	each
For CADD-Legacy® pumps		
50-/100-ml Reusable Pouch Accommodates pump with 50/100-ml Medication Cassette reservoir	21-6260-24	each
250-/500-ml Reusable Pouch Accommodates pump with 50/100-ml medication Cassette reservoir	21-6265-24	each

Single-Use Pouches

Product	Product Code	Unit
For CADD-Prizm® pumps, all models		
Navy 50-/100-ml Pump Pouches	21-6129-24	10/box
Navy 250-/500-ml Pump Pouches	21-6131-24	10/box
For CADD-Legacy® pumps		
Multi-colour 50-/100-ml Pump Pouches	21-6161-24	10/box
Multi-colour 250-/500-ml Pump Pouches	21-6163-24	10/box

Pouch Straps

Product	Product Code	Unit
Shoulder Strap For use with 50-/100-ml pump pouch	21-2352-24	each
Shoulder Strap For use with 250-ml, 250-/500-ml, and 1 litre pump pouches; 50-/100-ml and 250-/500-ml dual pump pouches; Lock Box	21-2353-24	each
Backpack Shoulder Strap	21-6125-24	each

External Power Source Components (for CADD-Prizm® pumps, all models)

Product	Product Code	Unit
Power Pack with Rechargable, Replaceable Battery AC adaptor required for use	21-3801-04 21-3801-03	each each
Ni-MH Replacement Battery For use with 21-3800 and 21-3801 power pack	21-3801-04 21-3802-23	each each
AC Adaptor 110 volts (USA) Connector Note: This product is not CE marked	21-3815-01	each
AC Adaptor 220 volts (Europlug) Connector	21-3807-22	each
AC Adaptor 220 volts (UK) Connector	21-3809-20	each
AC Adaptor 240 volts Note: This product is not CE marked	21-3808-10	each

CADD-Prizm® Pump Accessories

Product	Product Code	Unit
Pole-mount Bracket Slides into recess on back of CADD-Prizm® pump or security shell to allow pole-mounting of pump or pump and security shell.	21-6118-24	each
Power and Data In/Out Cover Replacement cover for power and data in/out jack	21-6113-24	each

CADD-Legacy® Pump Accessories

Product	Product Code	Unit
Polemount Bracket For use with pole-mount bracket (21-6118)	21-6210-24	each
For CADD-Legacy® 1, CADD-Legacy® PLUS and CADD-Legacy® PCA pumps		
AC Adaptor 220 volts (Europlug) Connector	21-6206-26	each
AC Adaptor 220 volts (UK) Connector	21-6204-20	each
AC Adaptor 240 volts (Japan) Note: This product is not CE marked	21-6208-09	each
AC Adaptor 240 volts (Australia) Note: This product is not CE marked	21-6209-10	each

Accessories

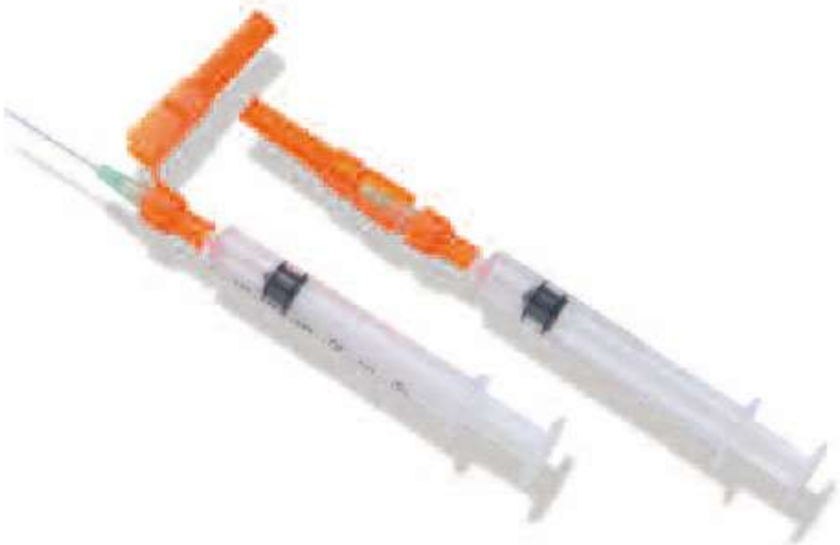
Product	Product Code	Unit
Battery Doors		
For CADD-Prizm® pumps – Standard	21-6110-24	each
For CADD-Legacy® pumps – Standard	21-6216-24	each
Pump Key for CADD-PCA®, CADD-Legacy® PCA and CADD-Prizm® pumps		
Pump Key	21-2303-24	each
Remote Dose Cords		
For use with CADD-Prizm® pumps	21-5814-22	each
For use with CADD-Legacy® PCA pumps	21-6220-24	each

PC to Pump Communications (For use with CADD-Prizm® and CADD-Legacy® pumps)

Product	Product Code	UCP Number	Unit
CADD-DIPLOMAT® System For Clinicians: (Must choose items from 1 and 2 for entire system)			
1 CD ROM for installing software on computer	21-6141-51	(01) 0 0610586 02224 4	each
2 For use with CADD-Prizm® pumps Interface cable/null modem cable to directly connect PC and CADD-Prizm® pump	21-6144-24	(01) 0 0610586 02590 0	each
For use with CADD-Legacy® pumps Interface cable/null modem cable to directly connect PC and CADD-Legacy® pump	21-6250-24	(01) 0 0610586 02177 3	each

Computer Requirements when using CADD-DIPLOMAT® System

- 486 or faster PC compatible computer (with an available 16 bit ISA slot for the internal modem) or an available RS232 serial port for an external modem.
- Windows® 95 or higher, or windows NT® 4.0.
- 8MB RAM (minimum).
- Hard Drive with at least 20MB available.



Sharps safety devices

Smiths Medical is helping to protect healthcare workers from exposure to sharps injuries through the introduction of a range of sharps safety devices.

At Smiths Medical, safety is the number one priority. The primary goal is to promote safety in every way and to create the safest possible environment for healthcare workers. Smiths Medical has been a leader in the prevention of blood-borne pathogen exposure and sharps safety for more than ten years. It continues to develop and introduce new and improved products that make sharps use as safe as possible for clinicians and healthcare workers.

The Smiths Medical POINT-LOK® device is handy enough to slip into a pocket and can be supplied as an individual item or incorporated into Select Custom Kits, providing effective protection for sharps from 16-30 gauge.

The Hypodermic Needle Pro® Ranges are available as individual items or pre-attached to syringes.

Specification
Hypodermic Needle Pro® – Syringe and Needle with Needle Protection Device

Syringe	Needle Gauge	Colour	Product Code
1ml	25G x 25mm (1")	orange	4211
3ml	20G x 38mm (1 1/2")	yellow	4230
3ml	20G x 25mm (1")	yellow	4231
3ml	21G x 38mm (1 1/2")	deep green	4232
3ml	21G x 25mm (1")	deep green	4233
3ml	22G x 38mm (1 1/2")	black	4234
3ml	22G x 25mm (1")	black	4235
3ml	23G x 25mm (1")	deep blue	4236
3ml	25G x 16mm (5/8")	orange	4237
3ml	25G x 25mm (1")	orange	4238
5ml	20G x 38mm (1 1/2")	yellow	4250
5ml	20G x 25mm (1")	yellow	4251
5ml	21G x 38mm (1 1/2")	deep green	4252
5ml	22G x 38mm (1 1/2")	black	4254
10ml	20G x 38mm (1 1/2")	yellow	4260
10ml	20G x 25mm (1")	yellow	4261
10ml	21G x 38mm (1 1/2")	deep green	4262
1ml Luer slip with rotating Needle-Pro device	25G x 16mm (5/8")	orange	4310
1ml Luer slip with rotating Needle-Pro device	26G x 13mm (1/2")	brown	4312E
1ml Luer slip with rotating Needle-Pro device	27G x 13mm (1/2")	grey	4313

Supplied in packs of 400
Conforms to ISO Colour Codes

Specification
Hypodermic Needle Pro® – Needle with Needle Protection Device

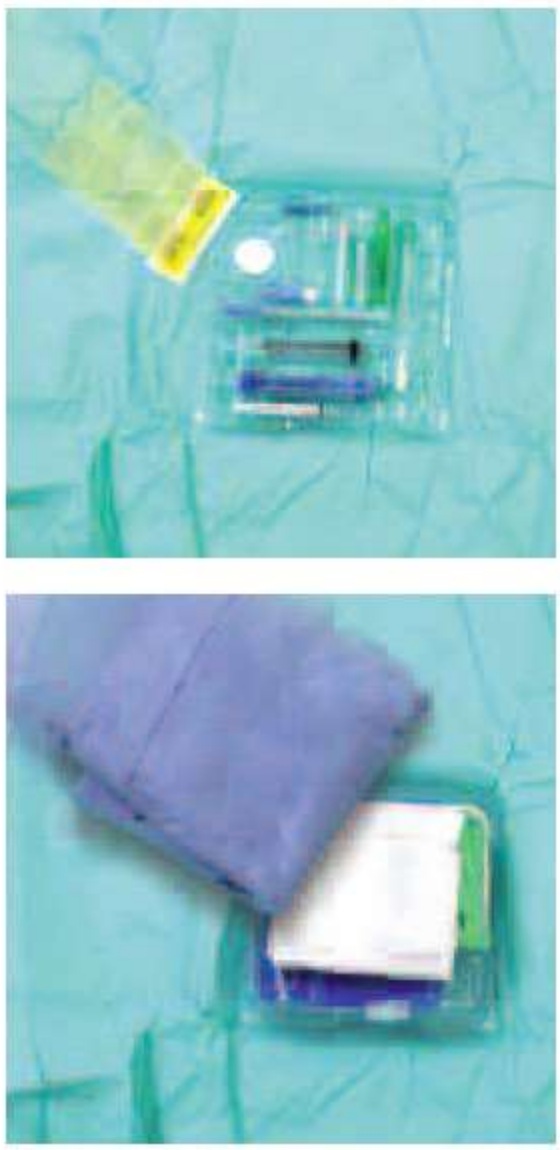
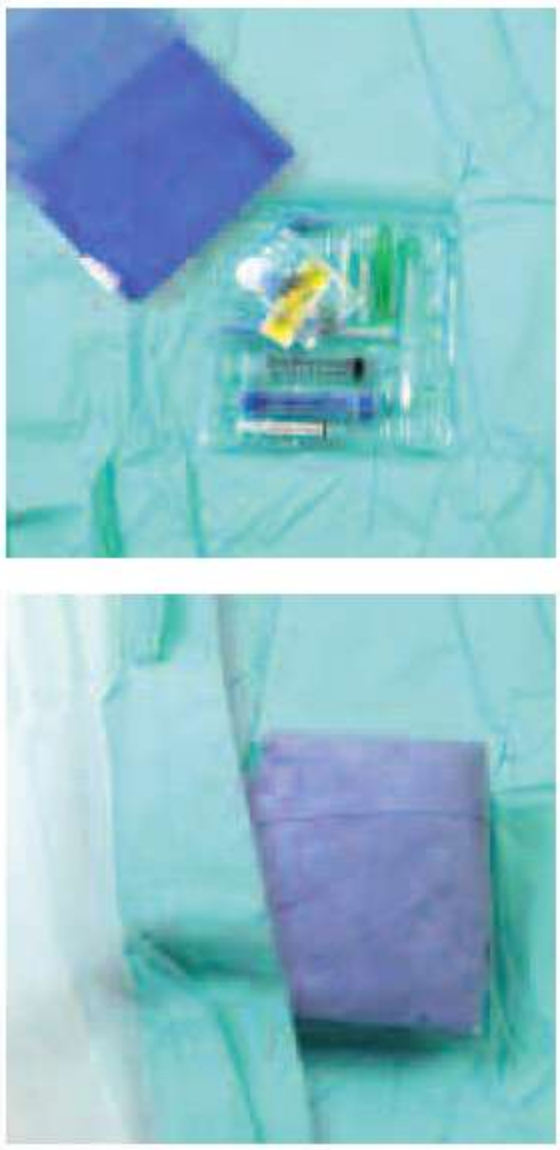
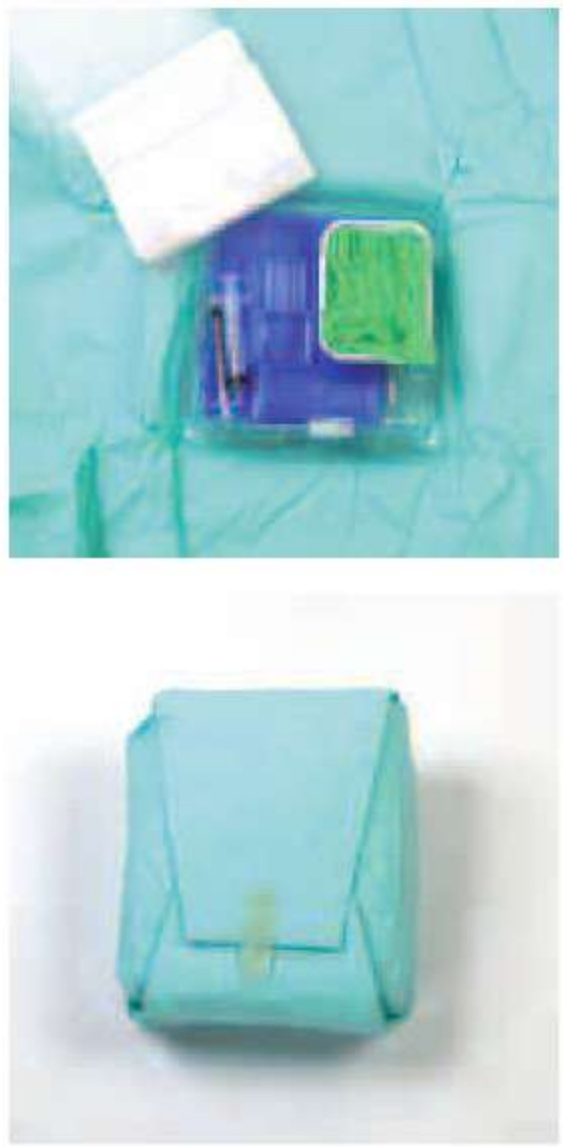
Needle Gauge	Colour	Product Code
18G x 38mm (1 1/2")	pink	4280
18G x 25mm (1")	pink	4281
19G x 38mm (1 1/2")	cream	4282E
19G x 25mm (1")	cream	4283E
20G x 38mm (1 1/2")	yellow	4284
20G x 25mm (1")	yellow	4285
21G x 38mm (1 1/2")	deep green	4286
21G x 25mm (1")	deep green	4287
22G x 38mm (1 1/2")	black	4288
22G x 25mm (1")	black	4289
22G x 31mm (1 1/4")	black	4296
23G x 25mm (1")	deep blue	4290
23G x 31mm (1 1/4")	deep blue	4297
25G x 16mm (5/8")	orange	4291
25G x 25mm (1")	orange	4292
25G x 16mm (5/8") with rotating Needle-Pro device	orange	4320*
26G x 13mm (1/2") with rotating Needle-Pro device	brown	4322E*
27G x 13mm (1/2") with rotating Needle-Pro device	grey	4323*

* For use with Luer slip syringes only. Supplied in packs of 800
Conforms to ISO Colour Codes

smiths

Select Custom Kits

Selected by you, assembled by Smiths Medical

PAINMANAGEMENT

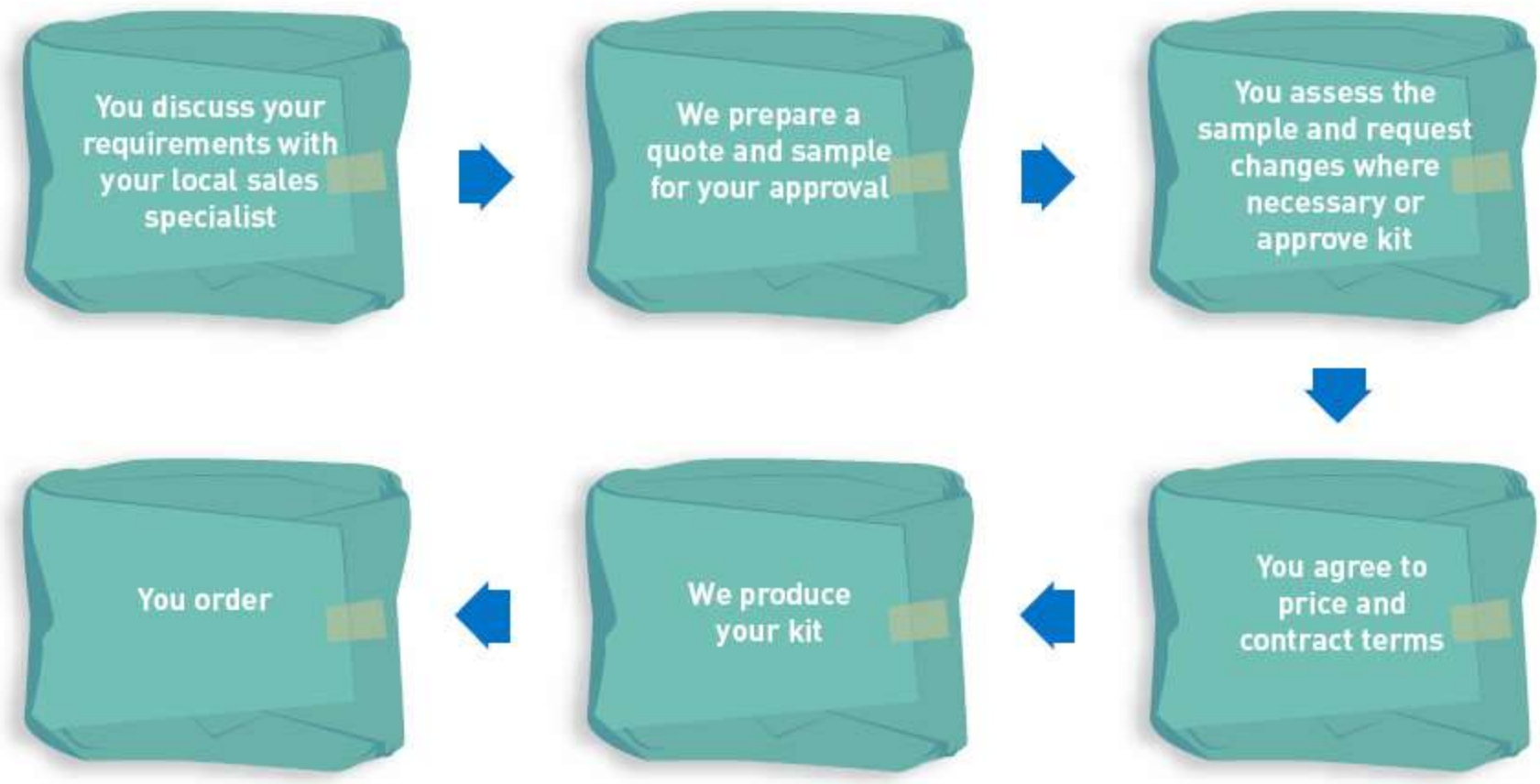
SELECT CUSTOM KITS

Just as all patients are individuals, so are the health professionals who care for them. Smiths Medical supplies standard ready-to-use packs for a number of procedures. We also supply Select Custom Kits, allowing us to treat our customers as individuals.

THE SELECT CUSTOM KIT service gives you the opportunity to customise your own kits to suit personal component preferences and operational needs.

With a Select Custom Kit all components are at hand ready for a procedure with the exact items specified in one convenient package. This reduces waste, and saves you time and money.

THE SELECT CUSTOM KITTING PROCESS



FOR MORE DETAILS CONTACT YOUR LOCAL SMITHS MEDICAL REPRESENTATIVE

THE DETAILS GIVEN IN THIS LEAFLET ARE CORRECT AT THE TIME OF GOING TO PRESS. THE COMPANY RESERVES THE RIGHT TO IMPROVE THE EQUIPMENT SHOWN.

For further information please call your local Smiths Medical distributor or Smiths Medical on +44 (0)1303 260551

Smiths Medical International Ltd

Hythe, Kent CT21 6JL UK
Tel: +44 (0)1303 260551 Fax: +44 (0)1303 266761
www.smiths-medical.com

Smiths is a trademarks of Smiths Group plc.
Literature No. LIT/PM/2563

smiths

Smiths Medical - a part of Smiths Group plc

EC Certification

EC DESIGN EXAMINATION CERTIFICATE
Directive 93/42/EEC for Medical Devices, Annex II (4)

We hereby declare that a design examination has been carried out on the devices(s) listed hereafter following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed hereafter conforms with the relevant provisions of Annex II Section 4 of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products*.

SMITHS MEDICAL ASD INC.

1265 Grey Fox Road, St Paul, MN 55112, USA

1. PORT-A-CATH® Peritoneal Implantable Access System
2. PORT-A-CATH® II Fluoro-Free® Implantable Venous Access
3. PORT-A-CATH® & PORT-A-CATH® II Epidural or Intraspinal Implantable Access System
4. P.A.S. PORT® Systems Fluoro-Free® Implantable Venous Access Systems
5. PORT-A-CATH® / PORT-A-CATH® II Vascular Access Systems
6. P.A.S. PORT® Systems Implantable Venous Access Systems
7. ProPort® Implantable Venous Access Systems
8. PORT-A-CATH®, PORT-A-CATH® II,and P.A.S. PORT® T2 POWER P.A.C.™Implantable Venous Access Systems with Power Injection Capability
9. PORT-A-CATH® II and P.A.S. PORT® T2 POWER P.A.C.™ Fluoro-Free® Implantable Venous Access Systems with Power Injection Capability

*For CE marking the class III devices covered by this certificate, an EC certificate according to Annex II (3) is also required.

Certificate Number: **058.1-03 DE**
Initial Certification Date: **09 August 1995**
Certificate Effective Date: **13 May 2016**
Certificate Expiry Date: **08 August 2020**

Barry A. Fitch
Head of Notified Body
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.
This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.
AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

Certificat CE

CERTIFICAT DE EXAMINARE CE DE TIP
Directiva 93/42/CEE pentru Dispozitive Medicale, Anexa II (4)

Declarăm prin prezenta că a fost efectuată o examinare a tipului dispozitivului(elor) specificate în continuare în prezenta, conform cerințelor legislației naționale britanice la care este supusă subsemnata, cu transpunerea Anexei II Secțiunea 4 la Directiva 93/42/CEE privind dispozitivele medicale. Certificăm că tipul dispozitivului(elor) menționate în continuare în prezenta este în conformitate cu prevederile relevante ale Anexei II Secțiunea 4 din legislația menționată mai sus și, prin urmare, organizația are dreptul de a utiliza marcajul CE 0473 pe produsele specificate mai jos *.

SMITHS MEDICAL ASD INC.

1265 Grey Fox Road, St Paul, MN 55112, SUA

1. Sistem implantabil de acces peritoneal PORT-A-CATH®
2. Acces implantabil venos PORT-A-CATH® II Fluoro-Free®
3. Sistem implantabil de acces epidural sau intraspinal PORT-A-CATH® & PORT-A-CATH® II
4. Sisteme implantabile de acces venos P.A.S. PORT® Systems Fluoro-Free®
5. Sisteme de acces vascular PORT-A-CATH® / PORT-A-CATH® II
6. Sisteme implantabile de acces venos P.A.S. PORT®
7. Sisteme implantabile de acces venos ProPort®
8. Sisteme implantabile de acces venos cu capacitate de injectare PORT-A-CATH®, PORT-A-CATH® II,și P.A.S. PORT® T2 POWER P.A.C.™
9. Sisteme implantabile de acces venos cu capacitate de injectare PORT-A-CATH® II and P.A.S. PORT® T2 POWER P.A.C.™ Fluoro-Free®

*Pentru a primi marcajul CE, dispozitivele din clasa III acoperite de acest certificat necesită și un certificat CE conform Anexei II (3).

Număr Certificat: Inițial 058.1-03 DE
Data Certificării: 09 August 1995
Data efectivă a certificării: 13 Mai 2016
Data expirării certificării: 08 August 2020

Semnătură indescifrabilă

Barry A. Fitch
Directorul Organismului Notificat
AMTAC Certification Services Limited, Milton Keynes, UK
Acest certificat este proprietatea AMTAC Certification Services Ltd

La eliberarea acestui certificat, Intertek nu își asumă responsabilitatea față de oricare parte alta decât Clientul, și atunci doar în conformitate cu Acordul de Certificare agreat. Valabilitatea acestui certificat este supusă menținerii, de către organizație, a sistemului în conformitate cu cerințele Intertek pentru certificarea sistemelor.
Valabilitatea acestuia poate fi confirmată la certificate.validation@intertek.com sau prin scanarea codului din dreapta cu un smartphone.
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Acest certificat rămâne proprietatea Intertek, căreia îi va fi returnat la cerere.

Certificarea este supusă menținerii, de către organizație, a sistemului acesteia în conformitate cu regulamentele specificate în acest certificat și permite evaluări regulate și în urma cerințelor contractate ale Organismului Notificat.
AMTAC Certification Services Limited este Organsim Notificat conform Directivei 93/42/CEE pentru dispozitivele medicale, cu număr de identificare 0473.

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

EC Certification

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

SMITHS MEDICAL, ASD, INC

160 Weymouth Street, Rockland, MA 02370, USA

Warming Units, Blankets and Accessories
Infusion Sets
Aesophageal Stethoscopes; 9 to 24 Fr
Aerosol cloud enhancer
Bypass valve for HME/HCH
Low-flow breathing exerciser
Incentive spirometers
Positive airway pressure therapy system
Vibratory positive expiratory pressure therapy systems with or without small volume nebulizer
Positive expiratory pressure therapy system
As per the attached schedule

Certificate Number:	**171 CE**
Initial Certification Date:	**24 July 1998**
Certificate Effective Date:	**24 July 2013**
Certificate Expiry Date:	**23 July 2018**

Brian Johnson ~ Authorised Signatory

AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd a wholly owned subsidiary of Intertek Holdings Ltd

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.
This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.
AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

ROMÂNIA MINISTERUL JUSTIȚIEI OLARU RUXANDRA Traducător autorizat FRANCEZĂ-ENGLEZĂ AUTORIZAȚIE NR.

PRODUCT SCHEDULE FOR CERTIFICATE 171 CE
SMITHS MEDICAL ASD, INC

Slow Flow Fluid Warming Unit
Slow Flow I V Infusion Sets
Slow Flow Fluid Warming Unit Accessories
Fluid Warming Units, Fast Flow
Fast Flow Accessory Equipment
Fast Flow I.V. Infusion Sets, Sterile fluid path
Fast Flow I.V. Infusion Sets, Accessory
Irrigating Sets, disposable
Slow Flow Fluid Warming units with PEMS (Programmable Medical Systems)
Slow Flow I.V. Infusion Sets for PEMS units
Convective Warming units
Convective Warming Blankets Sterile
Convective Warming Blankets Non-Sterile
Convective Warming Accessories
General Purpose Temperature Probes, Esophageal/Rectal 9 to 12 French
Myocardial Temperature Probes, Foley Catheter 3 to 30 mm
Temperature Probes, Foley Catheter 8 to 18 French
Temperature Probes, Skin, adult to neonate
Temperature Probes, Tympanic; adult and paediatric
Aesophageal Stethoscopes; 9 to 24 Fr
Aerosol cloud enhancer
Bypass valve for HME/HCH
Low-flow breathing exerciser
Incentive spirometers
Positive airway pressure therapy system
Vibratory positive expiratory pressure therapy systems with or without small volume nebulizer
Positive expiratory pressure therapy system

Initial Certification Date: 24 July 1998
Certificate Effective Date: 24 July 2013

Brian Johnson ~ Authorized Signatory

ROMANIA MINISTERUL JUSTIȚIEI
OLARU ALEXANDRA
Traducător autorizat FRANCEZĂ - ENGLEZĂ
AUTORIZAȚIE NR.

Traducere din limba engleză

Certificare CE

Intertek

SISTEM COMPLET DE ASIGURARE A CALITĂȚII

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzând (4)

Declarăm prin prezenta că o examinare a sistemului complet de asigurare a calității menționat mai jos a fost efectuată conform cerințelor legislației naționale din UK care ne guvernează, transpunând Anexa II (cu excepția secțiunii 4) a Directivei 93/42/CEE privind dispozitivele medicale. Certificăm că sistemul complet de asigurare a calității este în conformitate cu prevederile relevante ale directivei menționate mai sus, iar rezultatul îi dă dreptul organizației să folosească marcajul CE 0473 pe produsele enumerate mai jos.

SMITHS MEDICAL, ASD, INC

160 Weymouth Street Rockland, MA 02370 SUA

Unități de încălzire, pături și accesorii

Perfuzoare

Stetoscoape esofagiene, 9-24 Fr

Amplificator nor aerosoli

Valvă bypass pentru HME/HCH

Aparat pentru exerciții respiratorii cu flux redus

Spirometre de stimulare

Sistem de terapie cu presiune pozitivă a căilor respiratorii

Sisteme de terapie cu presiune expiratorică pozitivă vibratoare cu sau fără nebulizator de volum mic

Sistem de terapie cu presiune expiratoare pozitivă

Conform listei atașate

Număr Certificat:	171 CE
Data inițială a certificării:	24 Iulie 1998
Data intrării în vigoare a certificatului:	24 Iulie 2013
Data expirării certificatului:	24 Iulie 2018

Brian Johnson - Semnatar autorizat – *Semnătură indescifrabilă*

AMTAC Certification Services Limited, Milton Keynes, UK

Prezentul Certificat este proprietatea AMTAC Certification Services Ltd o filială deținută integral de Intertek Holdings Ltd

În emiterea prezentului certificat, AMTAC nu își asumă nicio răspundere către nicio parte, alta decât Clientul și atunci numai în conformitate cu Acordul de Certificare convenit. Valabilitatea prezentului certificat este condiționată de menținerea sistemului în conformitate cu cerințele Intertek pentru certificarea sistemelor. Valabilitatea poate fi confirmată prin email la certificate.validationtaiintertek.com sau scanând codul din dreapta cu un smpartphone. Prezentul certificat este pentru utilizarea exclusivă a clientului AMTAC și este furnizat în conformitate cu acordul dintre AMTAC și Clientul său. Responsabilitatea și răspunderea AMTAC sunt limitate la termenii și condițiile acordului. AMTAC nu își asumă răspunderea față de nicio parte, cu excepția Clientului, conform acordului, pentru nicio pierdere, cheltuială sau daună cauzată de folosirea prezentului Certificat. Doar Clientul este autorizat să permită copierea și distribuirea prezentului Certificat. Orice utilizare a numelui AMTAC sau a mărcilor sale pentru vânzarea și promovarea materialelor, produselor sau serviciilor testate trebuie aprobată în prealabil în scris de AMTAC.

Prezentul certificat rămâne proprietatea societății Intertek, căreia trebuie să îi fie returnat la cerere.

Certificarea este condiționată de păstrarea sistemului organizației în conformitate cu reglementările prevăzute în prezentul certificat și sub rezerva evaluărilor periodice și a respectării cerințelor contractate ale Organismului Notificat.

AMTAC Certification Services Limited este un Organism Notificat în conformitate cu Directiva 93/42/CEE privind dispozitivele medicale, cu numărul de identificare 0473.

ROMÂNIA MINISTERUL JUSTIȚIEI OLARU RUXANDRA Traducător autorizat FRANCEZĂ - ENGLEZĂ AUTORIZAȚIE Nr. 20615

Traducere din limba engleză

LISTA PRODUSELOR PENTRU CERTIFICATUL 171 CE
SMITHS MEDICAL, ASD, INC

Intertek

Unitate de încălzire fluide cu debit mic

Perfuzoare I.V. cu debit mic

Accesorii unitate de încălzire fluide cu debit mic

Unități de încălzire fluide, Debit mare

Echipamente accesorii debit mare

Perfuzoare I.V. cu debit mare, circuit fluid steril

Perfuzoare I.V. cu debit mare, Accesoriu

Irigatoare, de unică folosință

Unități de încălzire fluide cu debit mare cu PEMS (sisteme medicale programabile)

Perfuzoare I.V. cu debit mic pentru unități PEMS

Unități de încălzire convective

Pături de încălzire convective sterile

Pături de încălzire convective nesterile

Accesorii de încălzire convective

Sonde-termometre generale, Esofagiene/rectale 9-12 Francez

Sonde termometre miocardice, Cateter Foley 8 - 30 mm

Sonde termometre, Cateter Foley 8 - 18 Francez

Sonde termometre, Piele, adulți - nou-născuți

Sonde termometre, timpanice; pentru adulți și pediatrice

Stetoscoape esofagiene, 9-24 Fr

Amplificator nor aerosoli

Valvă bypass pentru HME/HCH

Aparat pentru exerciții respiratorii cu flux redus

Spirometre de stimulare

Sistem de terapie cu presiune pozitivă a căilor respiratorii

Sisteme de terapie cu presiune expiratorică pozitivă vibratoare cu sau fără nebulizator de volum mic

Sistem de terapie cu presiune expiratoare pozitivă

Data inițială a certificării: 24 Iulie 1998

Data intrării în vigoare a certificatului: 24 Iulie 2013

Brian Johnson - Semnatar autorizat – *semnătură indescifrabilă*

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 669121**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

By Royal Charter

Certificate No: CE 669121

Certificate Scope:

The design, development and manufacture of:

Sterile Disposable infusion kits including cassette, tubes, connectors, needles

Patient warming units

Blood and Fluid Warmers units

Sterile Blood and Fluid Warmers disposables sets

Sterile Central Implantable Access Systems

Sterile Peripheral Implantable Access Systems

Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets.

First Issued: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
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A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 USA	**Manufacture**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	**Gamma Sterilization**
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	**Design** **Manufacture**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	**Manufacture**
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	**Regulatory Compliance**
Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	**Manufacture**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF United Kingdom	**EU Representative**
Sterigenics US, LLC 10811 Withers Cover Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	**Gamma Sterilization**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**

Date: **2018-05-09**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Date	Reference Number	Action
20 July 2017	8691798	First issue, transferred from another notified body.
Current	8893340	Renewal, scope rewording, scope reduction, subcontractor removal, correction of subcontractor address and activities

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Nr. **CE 669121**

Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Cu privire la:

A se vedea fila cu domeniul de aplicare al certificatului.

pe baza examinării noastre efectuate asupra sistemului de asigurare a calității, în temeiul cerințelor Directivei Consiliului 93/42/CEE, Anexa II cu excepția Secțiunii 4. Sistemul de asigurare a calității întrunește cerințele directivei. Pentru plasarea pe piață a produselor din Clasa III, este necesar un certificat conform Anexei II secțiunea 4.

Pentru și în numele BSI, Organism Notificat pentru Directiva de mai sus (Organism Notificat Numărul 0086):

Semnătură indescifrabilă
Stewart Brain, Director Conformitate & Risc-
Dispozitive Medicale

MINISTERUL JUSTIȚIEI
MUȘUROIA
MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Prima ediție: **20.07.2017** Data: **09.05.2018** Data expirării: **18.03.2023**

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Valabilitatea acestui certificat este condiționată de menținerea sistemului calității în cerințele Directivei, demonstrate prin activitățile de supraveghere impuse de Organismul Notificat. Această aprobare exclude toate produsele create și/ sau fabricate de o parte terță în numele companiei numite în prezentul certificat, dacă nu se agreează în mod specific cu BSI.
Prezentul certificat a fost emis în formă electronică și este supus condițiilor contractului.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat nr. CE 669121

Domeniul de aplicare al Certificatului:

Proiectarea, dezvoltarea și fabricarea următoarelor produse:

Kit-uri de infuzie sterile, de unica folosinta, inclusiv casete, tuburi, conectori, ace

Unitati de incalzire pacient

Unitati de incalzire sange si fluide

Seturi sterile de unica folosinta incalzire sange si fluide

Sisteme sterile implantabile cu acces central

Sisteme sterile implantabile cu acces periferic

Acele aspecte din Anexa II cu privire la asigurarea și menținerea condițiilor sterile pentru paturici incalzire convectiva.

Prima ediție: **20.07.2017** Data: **09.05.2017** Data expirării: **18.03.2023**

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****

Subsemnata **MUSUROIA MIRELA,** traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

MINISTERUL JUSTIȚIEI MUȘUROIA MIRELA Aut. Nr. 2769 Engleză/Franceză TRADUCĂTOR AUTORIZAT

Traducător autorizat

Nr. 2769/2015

Valabilitatea acestui certificat este condiționată de menținerea sistemului calității în cerințele Directivei, demonstrate prin activitățile de supraveghere impuse de Organismul Notificat. Această aprobare exclude toate produsele create și/ sau fabricate de o parte terță în numele companiei numite în prezentul certificat, dacă nu se agreează în mod specific cu BSI.
Prezentul certificat a fost emis în formă electronică și este supus condițiilor contractului.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Subcontractor:	**Serviciu(ii) livrat(e)**
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 SUA	**Producție**
Isomedix Operations Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 SUA	**Sterilizare ETO**
Isomedix Operations Inc. 7685 Saint Andrews Avenue San Diego California 92154 SUA	**Sterilizare ETO**

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Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Isomedix Operations Inc. 43425 Business Park Drive Temecula California 92590 SUA	**Sterilizare ETO**
Isomedix Operations Inc. 23 Elizabeth Drive Chester New York 10918 SUA	**Sterilizare gamma**
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 SUA	Proiectare Producție

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Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Smiths Healthcare Manufacturing S.A de C.V. Avenida Calidad nr. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexic	**Producție**
Smiths Medical ASD, Inc. 1265 Grey Fox Road St Paul Minnesota 55112 SUA	**Respectarea reglementarilor**
Smiths Medical ASD, Inc. 3350 Granada Ave North Oakdale Minnesota 55128 SUA	**Producție**

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.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF Regatul Unit	**Reprezentanță UE**
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte Carolina de Nord 28278 SUA	**Sterilizare ETO**
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 SUA	**Sterilizare gamma**

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.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 SUA	**Sterilizare gamma**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 SUA	**Sterilizare ETO**
Sterigenics US, LLC 84 Park Road Queensbury 12804 New York SUA	**Sterilizare ETO**

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Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
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6000 Nathan Lane North
Minneapolis
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55442
SUA

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Data	Număr referință	Acțiune
20 iulie 2017	8691798	Prima ediție, transferată de la un alt organism notificat
Curentă	8893340	Reinnoire, reformulare domeniu de aplicare, reducere domeniu de aplicare, eliminare subcontractori, corectie adrese subcontractori si activitati

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.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

MED CERT®

Professional. Flexible. Medical Only.

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Smiths Medical ASD, Inc.
330 Corporate Woods Parkway
Vernon Hills, IL 60061-3107
USA

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

- **Water and saline solutions for inhalation**

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certificate is valid from 08 July 2015 until 07 July 2020

Report No.: 2708FS19F
Process No.: QS – 2708
Certificate No.: 2708GB414150706

Hamburg, 06 July 2015

MEDCERT Certification Body
(Rainer Klatt)

MEDCERT Identification No.: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 04 97063 001

Manufacturer:

Smiths Medical ASD, INC.
6000 Nathan Lane North
Minneapolis MN 55442
USA

EC-Representative:

Smiths Medical International Ltd.
1500 Eureka Park
Lower Pemberton
Ashford
Kent TN25 4BF
UNITED KINGDOM

Product Category(ies):

Vibratory positive expiratory devices, Incentive Spirometers, Silicone Laryngeal Mask, Oxygen Line accessory, Nasal Cannula, Oxygen Masks, Drainage bags, Oxygen tubing, Adult Face Tent, Disposable Anesthesia Face Masks

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72126765

Valid from: 2017-04-24
Valid until: 2021-09-21

Date, 2017-04-24

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 04 97063 001

Facility(ies):

Smiths Medical ASD, INC.
6000 Nathan Lane North, Minneapolis MN 55442, USA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Traducere din limba engleză

Certificat CE
Sistem de Asigurare a Calității
Directiva 93/42/CEE cu privire la Dispozitivele Medicale (MDD), Anexa II fără (4)
(Dispozitive din Clasa IIa, IIb sau III)

Nr. G1 17 04 97063 001

Producător:	**Smiths Medical ASD, INC.** 6000 Nathan Lane North Minneapolis MN 55442 SUA
Reprezentant CE:	**Smiths Medical International Ltd.** 1500 Eureka Park Lower Pemberton, Ashford Kent TN25 4BF REGATUL UNIT
Categorie(i) Produs	**Dispozitive monitorizare gaz medical, Spirometru de Stimulare, Mască Laringiană din Silicon, Accesoriu Linie Oxigen, Canulă Nazală, Măști de Oxigen, Pungi Drenaj, Tubulatură Oxigen, Mască Adulți, Măști Faciale Anestezie de Unică Folosință**

Organul de Certificare al TÜV SÜD Product Service GmbH declară că producătorul mai sus menţionat a implementat un sistem de asigurare a calităţii pentru proiectarea, producerea şi inspecţia finală a produselor respective / categorii de produs, în conformitate cu Anexa II MDD. Numitul sistem de asigurare a calităţii se conformează prevederilor Directivei şi se supune unei supravegheri periodice. Pentru comercializarea produselor clasa III un Certificat Anexa II (4) este obligatoriu. Vedeţi notele de pe pagina următoare.

Raport Nr.: **72126765**
Valabil de la: **24-04-2017**
Valabil până la: **21-09-2021**

Data, **24-04-2017**

Stefan Preiß
Semnătura – indescifrabil

TÜV SÜD Product Service GmbH este Organism de Notificare cu nr. de identificare 0123.

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Certificat CE
Sistem de Asigurare a Calității
Directiva 93/42/CEE cu privire la Dispozitivele Medicale (MDD), Anexa II fără (4)
(Dispozitive din Clasa IIa, IIb sau III)

Nr. G1 17 04 97063 001

Unități Producție: Smiths Medical ASD, INC.
6000 Nathan Lane North, Minneapolis MN 55442, SUA

****

Subsemnata **MUSUROIA MIRELA,** traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015

MINISTERUL JUSTIȚIEI
MUȘUROIA
MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 660825**

Issued To: **Smiths Medical ASD, Inc.**
10 Bowman Drive
Keene
New Hampshire
03431
USA

In respect of:

Spinal and combined spinal/epidural needles including Correct Inject Spinal Needles

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Item Number:	Description:
100/389/022	SPINAL MAXIPACK 22G
100/389/725CS	CORRECTINJECT SPINAL MAXIPACK 25G PENCIL POINT
100/389/726CS	CORRECTINJECT SPINAL MAXIPACK 26G PENCIL POINT
100/389/825	SPINAL MAXIPACK PENCIL POINT NEEDLE SIZE 25G
100/389/826	SPINAL MAXIPACK PENCIL POINT NEEDLE SIZE 26G
100/396/116	SPINAL/EPIDURAL SET LANCET SPINAL NEEDLE 26G/16G
100/396/318	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 27G LANCET 18G TUOHY
100/396/716	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 27G P/PNT 16G TUOHY
100/396/718	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 27G P/PNT 18G TUOHY
100/396/816	SPINAL/EPIDURAL SET PENCIL POINT SPINAL NEEDLE 26G/16G
100/396/916	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 26G P/PNT 16G TUOHY
100/491/116	SPINAL/EPIDURAL MINIPACK LANCET POINT NEEDLE 26G/16G
100/491/318	SPINAL/EPIDURAL MINIPACK WITH LOCK 27G LANCET 18G TUOHY
100/491/618	SPINAL/EPIDURAL MINIPACK PENCIL POINT NEEDLE 27G/18G
100/491/716	SPINAL/EPIDURAL MINIPACK WITH LOCK 27G P/PNT 16G TUOHY
100/491/718	SPINAL/EPIDURAL MINIPACK WITH LOCK 27G P/PNT 18G TUOHY
100/491/816	SPINAL/EPIDURAL MINIPACK PENCIL POINT NEEDLE 26G/16G
100/491/818	SPINAL/EPIDURAL MINIPACK PENCIL POINT NEEDLE 26G/18G
100/491/916	SPINAL/EPIDURAL MINIPACK WITH LOCK 26G P/PNT 16G TUOHY
100/492/815	25G PENCIL POINT SPINAL NEEDLE+ INTRODUCER, EXTRA LENGTH
100/492/816	26G EXTRA LENGTH SPINAL NEEDLEWITH 20G INTRODUCER NEEDLE
100/492/817	27G PENCIL POINT SPINAL NEEDLEWITH 20G INTRODUCER NEEDLE
100/492/715CS	CORRECTINJECT SPINAL NEEDLE SET 25G EXTRA LENGTH PENCIL POINT
100/492/716CS	CORRECTINJECT SPINAL NEEDLE SET 26G EXTRA LENGTH PENCIL POINT
100/492/717CS	CORRECTINJECT SPINAL NEEDLE SET 27G EXTRA LENGTH PENCIL POINT

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Item Number:	Description:
100/496/022	22G LANCET POINT SPINAL NEEDLESET
100/496/024	24G LANCET POINT SPINAL NEEDLESET
100/496/025	25G LANCET POINT SPINAL NEEDLESET
100/496/026	26G LANCET POINT SPINAL NEEDLESET
100/496/027	27G LANCET SPINAL NEEDLE SET
100/496/122	SPINAL NEEDLE SET 22G PENCIL POINT NEEDLE
100/496/124	24G SPINAL NEEDLE SET (PENCIL POINT)
100/496/125	SPINAL NEEDLE SET 25G PENCIL POINT NEEDLE
100/496/126	SPINAL NEEDLE SET 26G PENCIL POINT NEEDLE
100/496/127	27G PENCIL SPINAL NEEDLE SET
100/496/222CS	CORRECTINJECT SPINAL NEEDLE SET 22G PENCIL POINT
100/496/224CS	CORRECTINJECT SPINAL NEEDLE SET 24G PENCIL POINT
100/496/225CS	CORRECTINJECT SPINAL NEEDLE SET 25G PENCIL POINT
100/496/226CS	CORRECTINJECT SPINAL NEEDLE SET 26G PENCIL POINT
100/496/227CS	CORRECTINJECT SPINAL NEEDLE SET 27G PENCIL POINT
100/497/125	SPINAL MIDI-TRAY 25G PENCIL POINT SPINAL NEEDLE
100/497/126	SPINAL MIDI-TRAY 26G PENCIL POINT SPINAL NEEDLE
100/497/225CS	CORRECTINJECT SPINAL MIDI-TRAY 25G PENCIL POINT
100/497/226CS	CORRECTINJECT SPINAL MIDI-TRAY 26G PENCIL POINT
100/497/227CS	CORRECTINJECT SPINAL MIDI-TRAY 27G PENCIL POINT
921/025/0180	25G CUSTOM PACK
921/116/0121	CUSTOM RA TRAY
921/127/0198	16G/27G CSECURE CUSTOM KIT

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Item Number:	Description:
922/025/0163	25G SPINAL PACK,POOLE HOSPITAL 10/CA
922/025/0319	SET ANESTESIA ESPINAL PUNTA LAPIZ 25G
922/025/0564	25G SPINAL CUSTOM KIT
922/025/0604	25G SPINAL CUSTOM KIT
922/025/0665	25G SPINAL CUSTOM KIT
922/027/0285	27G SPINAL CUSTOM PACK
922/027/0319	27G SPINAL CUSTOM KIT
922/027/0415	27G SPINAL CUSTOM KIT
922/027/0593	27G SPINAL CUSTOM SET
922/116/0302	16G/26G COMBINED SPINAL EPI PK NORF/NORWICH HOSP
922/116/0412	16/26G CSE CUSTOM KIT
922/118/0412	18/26G CSE CUSTOM KIT
922/126/0382	16G/26G CSECURE CUSTOM
922/127/0272	16G/27G CSECURE CUSTOM KIT NORTHWICK PARK HOSPITAL
922/127/0323	6G/27G CSE CUSTOM KIT
922/127/0372	CSE CUSTOM PACK
922/127/0383	16G/27G CSE CUSTOM KIT
922/127/0441	16G/27G CSECURE CUSTOM KIT
922/127/0657	16/27G CUSTOM SET 10/BX
924/026/0123	SPINAL NEEDLE EXTRA LENGTH
924/027/0157	27G SPINAL N'DLE
928/118/0001	18G/27G CSECURE CUSTOM KIT
928/118/0008	18G/27G CUSTOM KIT + CSECURE

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Item Number:	Description:
931/127/0065	18G/27G/CSECURE CUS KIT
932/025/0022	25G SPINAL PACK
932/025/0157	25G SPINAL CUSTOM KIT
932/025/0162	25G SPINAL CUST KIT
932/025/0163	25G SPINAL CUSTOM KIT
932/025/0464	25G SPINAL PACK
932/025/0519	25G SPINAL CUSTOM KIT
932/025/0519CS	25G SPINAL CUSTOM KIT
932/025/0547	25g SPINAL CUSTOM KIT
932/026/0516	26G SPINAL CUSTOM PACK
932/026/0546	26g SPINAL CUSTOM KIT
932/027/0388	27G SPINAL CUSTOM KIT
932/027/0458	27G SPINAL CUSTOM KIT
932/027/0498	27G SPINAL CUSTOM KIT
932/027/0612	27G CUSTOM KIT
932/027/0657	27G SPINAL HELSINGER MODEL
932/116/0104	16G/26G CSECURE
932/116/0517	16G/26G CSECURE CUSTOM KIT
932/126/0668	16G/26G CSECURE CUSTOM KIT
932/127/0100	18G/27G EPIDURAL/SPINAL
932/127/0479	18G/27G CSECURE CUSTOM PACK
932/127/0696	18G/27G CSECURE CUSTOM KIT
934/024/0006	24G SPINAL PACK

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Item Number:	Description:
934/027/0000	27G SPINAL KIT
934/127/0001	16/27G CSECURE EPIDURAL KIT
936/025/0205	25G SPINL CUST PACK
936/027/0205	27G SPINL CUST PCK
936/118/0130	18G/27G EPIDUL/SNL CUST KIT W/SECURE
936/118/0132	18G/27G CSECURE CUSTOM KIT
937/025/0047	25G SPINAL SET
937/025/0102	25G SPINAL KIT SUS LUND/REGIONAL SKANE
937/027/0096	27G SPINAL CUSTOM KIT
937/027/0108	27G SPINAL KIT SUS LUND/REGIONAL SKANE
937/127/0040	18G/27G CSEcure CUSTOM KIT
937/127/0048	18G/27G CSE CUSTOM KIT
9EPD-102002	SPINAL SET 25G
9EPD-102003	SPINAL SET 27G
9EPD-122001	SPINAL SET 25G
9EPD-122001EVKH	SPINAL SET 25G
9EPD-401002	SPINAL SET 25G
9EPD-502592	SPINAL SET 26G
9EPD-528002	SPINAL SET 25G
9EPD-590653	SPINAL SET 26G
9EPD-602001	SPINAL SET 25G
9EPD-740002	SPINAL SET 27G
9EPD-803604	CSE SET 16G/26G

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Item Number:	Description:
9EPD-803605	CUSTOM SPINAL SET 26 G
9EPD-833001	SPINAL CUSTOM PACK
9EPD-849002	SPINAL SET, 22G
9EPD-877501	SPINAL SET 26G
A3562-24	LUMBAR PUNCTURE (EDD) W/O DRUGS
A3808-24	LUMBAR TRAY (EDD) W/O DRUGS
A4062-22	LUMBAR TRAY (EDD) W/O DRUGS
A4075-22	LUMBAR TRAY (EDD) W/O DRUGS
E619 22G	22G SPINAL MAXIPACK
E620 25G	25G SPINAL MAXIPACK
EPSPCC0001	27G SPINAL SET
G421	26G SPINAL MAXIPACK
G888	24G SPINAL MAXIPACK ATRAUMATIC
G972	27G SPINAL MAXIPACK
G973	25G SPINAL MAXIPACK
J651/61	25G SPINAL CUSTOM MAXIPACK
J653/61	18/27G CSE CUSTOM MAXIPACK
J654/61	18/25G CSE CUSTOM MAXIPACK
L741-61	25G WHITACRE SPINAL NEEDLE SINGLE PACKED
L746-61	22G SPINAL NEEDLE -QUINCKE SINGLE PACKED
M121	24G ATRAUMATIC SPINAL NEEDLE INTRODUCER
M122	25G WHITACRE SPINAL NEEDLE WITH INTRODUCER

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Item Number:	Description:
M145	18/25G CSE NEEDLE SET WHITACRE
M146	18/25G CSE MINIPACK WHITACRE
M341	29G QUINCKE SPINAL NEEDLE WITH INTRODUCER
M729-61	27G WHITACRE SPINAL NEEDLE WITH INTRODUCER
MAX251	SPINAL MAXIPACK 25G
MAX261	SPINAL MAXIPACK 26G
MAX271	SPINAL MAXIPACK 27G
SPICC0001	SPINAL SET 27g
SPIFC00302	SPINAL SET 25G
SPIFC00902	SPINAL SET 25G
928/127/0016	18G/27G CUSTOM KIT SEQUENCIAL CSECURE C. HOSPITALAR 10/BX
EPICC0018	CSE PROCEDURESET - GENTOFTE
SPICC0017	SPINALSET SLL, 25G 10/BX
SPICC0012	Custom Spinal Sg ShotTray
922/025/0345	25G SPINAL CUSTOM KIT

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Date	Reference Number	Action
Current	10166127	First issue. Transfer from another Notified Body and certificate renewal.

First Issued: **2017-06-16** Date: **2017-06-16** Expiry Date: **2022-06-15**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

By Royal Charter

Certificat CE – Examinarea proiectului

Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa II, Secțiunea 4

Nr. **CE 660825**

Emis pentru: **Smith Medical ASD, Inc.**
10 Bowman Drive
Keene
New Hampshire
03431
SUA

Cu privire la:
Ace spinale si combinate – spinale/epidurale, incluzand ace spilale pentru injectie corecta.

BSI a examinat proiectul, conform cerințelor Directivei Consiliului 93/42/CEE, Anexa II, Secțiunea 4. Proiectul îndeplinește cerințele directivei. Pentru plasarea pe piață a acestor produse este necesar un certificat aditional, prevazut de Anexa II secțiunea 4.

Pentru și în numele BSI, Organism de Notificare pentru Directiva de mai sus (Număr Organism de Notificare 0086):

Semnătura – indescifrabilă
Stewart Brain, Director Conformitate și Risc
Dispozitive Medicale

Prima emitere: **16-06-2017** Data: **16-06-2017** Data expirării: **15-06-2022**

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Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.
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Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK Membră a Grupului de Societăți BSI.

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S.C. GRAZIA PRICE MEDICAL IMPORT EXPORT S.R.L. Conform cu originalul

MINISTERUL JUSTIȚIEI MUȘUROIA MIRELA Ad. Nr. 2768 TRADUCĂTOR AUTORIZAT

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Numarul articolului:	Descriere:
100/389/022	MAXIPACHET SPINAL 22G
100/389/725CS	MAXIPACHET SPINAL CORRECTINJECT 25G VARF CREION
100/389/726CS	MAXIPACHET SPINAL CORRECTINJECT 26G VARF CREION
100/389/825	MAXIPACHET SPINAL VARF CREION DIMENSIUNE AC 25G
100/389/826	MAXIPACHET SPINAL VARF CREION DIMENSIUNE AC 26G
100/396/116	SET SPINAL/EPIDURAL LANTETA SPINALA AC 26G/16G
100/396/318	SET AC SPINAL/EPIDURAL CU AMBOU 27G LANTETA 18G TUOHY
100/396/716	SET AC SPINAL/EPIDURAL CU AMBOU 27G P/PNT 16G TUOHY
100/396/718	SET AC SPINAL/EPIDURAL CU AMBOU 27G P/PNT 18G TUOHY
100/396/816	SET SPINAL/EPIDURAL VARF CREION AC SPINAL 26G/16G
100/396/916	SET AC SPINAL/EPIDURAL CU AMBOU 26G P/PNT 16G TUOHY
100/491/116	MINIPACHET SPINAL/EPIDURAL AC CU VARF LANTETA 26G/16G
100/491/318	MINIPACHET SPINAL/EPIDURAL CU AMBOU 27G LANTETA 18G TUOHY
100/491/618	MINIPACHET SPINAL/EPIDURAL VARF CREION AC 27G/18G
100/491/716	MINIPACHET SPINAL/EPIDURAL CU AMBOU 27G P/PNT 16G TUOHY
100/491/718	MINIPACHET SPINAL/EPIDURAL CU AMBOU 27G P/PNT 18G TUOHY
100/491/816	MINIPACHET SPINAL/EPIDURAL VARF CREION AC 26G/16G
100/491/818	MINIPACHET SPINAL/EPIDURAL VARF CREION AC 26G/18G
100/491/916	MINIPACHET SPINAL/EPIDURAL CU AMBOU 26G P/PNT 16G TUOHY
100/492/815	25G AC SPINAL CU VARF CREION+ INTRODUCTOR, EXTRALUNG
100/492/816	26G AC SPINAL EXTRALUNG CU 20G AC INTRODUCTOR
100/492/817	27G AC SPINAL CU VARF CREION CU 20G AC INTRODUCTOR
100/492/715CS	SET AC SPINAL CORRECTINJECT 25G EXTRALUNG VARF CREION
100/492/716CS	SET AC SPINAL CORRECTINJECT 26G EXTRALUNG VARF CREION
100/492/717CS	SET AC SPINAL CORRECTINJECT 27G EXTRALUNG VARF CREION

Prima emitere: **2017-06-16** Data: **2017-06-16** Data expirării: **2022-06-15**

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Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Numarul articolului:	Descriere:
100/496/022	22G SET AC SPINAL CU VARF LANTETA
100/496/024	24G SET AC SPINAL CU VARF LANTETA
100/496/025	25G SET AC SPINAL CU VARF LANTETA
100/496/026	26G SET AC SPINAL CU VARF LANTETA
100/496/027	27G SET AC SPINAL CU VARF LANTETA
100/496/122	SET ACESPINAL 22G VARF CREION AC
100/496/124	24G SET ACESPINAL (VARF CREION)
100/496/125	SET ACESPINAL 25G VARF CREION AC
100/496/126	SET ACESPINAL 26G VARF CREION AC
100/496/127	27G SET AC SPINAL CU VARF CREION
100/496/222CS	SET AC SPINAL CORRECTINJECT 22G VARF CREION
100/496/224CS	SET AC SPINAL CORRECTINJECT 24G VARF CREION
100/496/225CS	SET AC SPINAL CORRECTINJECT 25G VARF CREION
100/496/226CS	SET AC SPINAL CORRECTINJECT 26G VARF CREION
100/496/227CS	SET AC SPINAL CORRECTINJECT 27G VARF CREION
100/497/125	TRAIECT SPINAL MEDIU 25G AC SPINAL CU VARF CREION
100/497/126	TRAIECT SPINAL MEDIU 26G AC SPINAL CU VARF CREION
100/497/225CS	TRAIECT SPINAL MEDIU CORRECTINJECT 25G VARF CREION
100/497/226CS	TRAIECT SPINAL MEDIU CORRECTINJECT 26G VARF CREION
100/497/227CS	TRAIECT SPINAL MEDIU CORRECTINJECT 27G VARF CREION
921/025/0180	25G PACHET PERSONALIZAT
921/116/0121	TRAIECT RA PERSONALIZAT
921/127/0198	16G/27G CSECURE SET PERSONALIZAT

Prima emitere: **2017-06-16** Data: **2017-06-16** Data expirării: **2022-06-15**

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bsi.

By Royal Charter

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Numarul articolului:	Descriere:
922/025/0163	PACHET SPINAL,POOLE HOSPITAL 25G 10/CA
922/025/0319	SET SPINAL ANESTEZIE PUNTA LAPIZ 25G
922/025/0564	25G SET SPINAL PERSONALIZAT
922/025/0604	25G SET SPINAL PERSONALIZAT
922/025/0665	25G SET SPINAL PERSONALIZAT
922/027/0285	27G PACHET SPINAL PERSONALIZAT
922/027/0319	27G SET SPINAL PERSONALIZAT
922/027/0415	27G SET SPINAL PERSONALIZAT
922/027/0593	27G SET SPINAL PERSONALIZAT
922/116/0302	16G/26G PACHET COMBINAT SPINAL/EPIDURALPK NORF/NORWICH HOSP
922/116/0412	16/26G CSE SET PERSONALIZAT
922/118/0412	18/26G CSE SET PERSONALIZAT
922/126/0382	16G/26G CSECURE PERSONALIZAT
922/127/0272	16G/27G CSECURE SET PERSONALIZAT NORTHWICK PARK HOSPITAL
922/127/0323	6G/27G CSE SET PERSONALIZAT
922/127/0372	CSE PACHET PERSONALIZAT
922/127/0383	16G/27G CSE SET PERSONALIZAT
922/127/0441	16G/27G CSECURE SET PERSONALIZAT
922/127/0657	16/27G SET PERSONALIZAT 10/CUTIE
924/026/0123	AC SPINAL EXTRALUNG
924/027/0157	27G SPINAL N'DLE
928/118/0001	18G/27G CSECURE SET PERSONALIZAT
928/118/0008	18G/27G SET PERSONALIZAT + CSECURE

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Prima emitere: **2017-06-16** Data: **2017-06-16** Data expirării: **2022-06-15**

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By Royal Charter

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

MUȘUROIA MIRELA Aut. Nr. 2769 TRADUCĂTOR AUTORIZAT

Emis pentru:

S.C. GRAZY PRICE MEDICAL IMPORT EXPORT S.R.L. Conform cu originalul

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Numarul articolului:	Descriere:
931/127/0065	18G/27G/CSECURE SET PERSONALIZAT
932/025/0022	25G PACHET SPINAL
932/025/0157	25G SET SPINAL PERSONALIZAT
932/025/0162	25G SET SPINAL PERSONALIZAT
932/025/0163	25G SET SPINAL PERSONALIZAT
932/025/0464	25G PACHET SPINAL
932/025/0519	25G SET SPINAL PERSONALIZAT
932/025/0519CS	25G SET SPINAL PERSONALIZAT
932/025/0547	25g SET SPINAL PERSONALIZAT
932/026/0516	26G PACHET SPINAL PERSONALIZAT
932/026/0546	26g SET SPINAL PERSONALIZAT
932/027/0388	27G SET SPINAL PERSONALIZAT
932/027/0458	27G SET SPINAL PERSONALIZAT
932/027/0498	27G SET SPINAL PERSONALIZAT
932/027/0612	27G SET PERSONALIZAT
932/027/0657	27G SPINAL HELSINGER MODEL
932/116/0104	16G/26G CSECURE
932/116/0517	16G/26G CSECURE SET PERSONALIZAT
932/126/0668	16G/26G CSECURE SET PERSONALIZAT
932/127/0100	18G/27G EPIDURAL/SPINAL
932/127/0479	18G/27G CSECURE PACHET PERSONALIZAT
932/127/0696	18G/27G CSECURE SET PERSONALIZAT
934/024/0006	24G PACHET SPINAL

Prima emitere: **2017-06-16** Data: **2017-06-16** Data expirării: **2022-06-15**

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Informatii suplimentare pentru CE 660825

Emis pentru:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Numarul articolului:	Descriere:
934/027/0000	27G SET SPINAL
934/127/0001	16/27G CSECURE EPIDURAL KIT
936/025/0205	25G PACHET SPINAL PERSONALIZAT
936/027/0205	27G PACHET SPINAL PERSONALIZAT
936/118/0130	18G/27G SET EPIDURAL/SPINAL PERSONALIZAT CU PROTECTIE
936/118/0132	18G/27G CSECURE SET PERSONALIZAT
937/025/0047	25G SET SPINAL
937/025/0102	25G SET SPINAL SUS LUND/REGIONAL SKANE
937/027/0096	27G SET SPINAL PERSONALIZAT
937/027/0108	27G SET SPINAL SUS LUND/REGIONAL SKANE
937/127/0040	18G/27G CSEcure - SET PERSONALIZAT
937/127/0048	18G/27G CSE SET PERSONALIZAT
9EPD-102002	SET SPINAL 25G
9EPD-102003	SET SPINAL 27G
9EPD-122001	SET SPINAL 25G
9EPD-122001EVKH	SET SPINAL 25G
9EPD-401002	SET SPINAL 25G
9EPD-502592	SET SPINAL 26G
9EPD-528002	SET SPINAL 25G
9EPD-590653	SET SPINAL 26G
9EPD-602001	SET SPINAL 25G
9EPD-740002	SET SPINAL 27G
9EPD-803604	CSE SET 16G/26G

Prima emitere: **2017-06-16** Data: **2017-06-16** Data expirării: **2022-06-15**

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By Royal Charter

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Numarul articolului:	Descriere:
9EPD-803605	SETN SPINAL PERSONALIZAT 26 G
9EPD-833001	PACHET SPINAL PERSONALIZAT
9EPD-849002	SET SPINAL, 22G
9EPD-877501	SET SPINAL 26G
A3562-24	PUNCTIE LOMBARA (EDD) FARA MEDICAMENTE
A3808-24	TRAIECT LOMBAR (EDD) FARA MEDICAMENTE
A4062-22	TRAIECT LOMBAR (EDD) FARA MEDICAMENTE
A4075-22	TRAIECT LOMBAR (EDD) FARA MEDICAMENTE
E619 22G	22G MAXIPACHET SPINAL
E620 25G	25G MAXIPACHET SPINAL
EPSPCC0001	27G SET SPINAL
G421	26G MAXIPACHET SPINAL
G888	24G MAXIPACHET SPINAL ATRAUMATIC
G972	27G MAXIPACHET SPINAL
G973	25G MAXIPACHET SPINAL
J651/61	25G MAXIPACHET SPINAL PERSONALIZAT
J653/61	18/27G CSE MAXIPACHET PERSONALIZAT
J654/61	18/25G CSE MAXIPACHET PERSONALIZAT
L741-61	25G WHITACRE AC SPINAL AMBALAT INDIVIDUAL
L746-61	22G AC SPINAL -QUINCKE AMBALAT INDIVIDUAL
M121	24G ATRAUMATIC AC SPINAL INTRODUCTOR
M122	25G WHITACRE AC SPINAL CU INTRODUCTOR

Prima emitere: **2017-06-16** Data: **2017-06-16** Data expirării: **2022-06-15**

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Informatii suplimentare pentru CE 660825

Emis pentru:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Numarul articolului:	Descriere:
M145	18/25G CSE SET ACE WHITACRE
M146	18/25G CSE MINIPACHET WHITACRE
M341	29G QUINCKE AC SPINAL cu INTRODUCTOR
M729-61	27G WHITACRE AC SPINAL cu INTRODUCTOR
MAX251	MAXIPACHET SPINAL 25G
MAX261	MAXIPACHET SPINAL 26G
MAX271	MAXIPACHET SPINAL 27G
SPICC0001	SET SPINAL 27g
SPIFC00302	SET SPINAL 25G
SPIFC00902	SET SPINAL 25G
928/127/0016	18G/27G SET PERSONALIZAT SECVENTIAL CSECURE C. HOSPITALAR 10/CUTIE
EPICC0018	CSE SET PROCEDURAL - GENTOFTE
SPICC0017	SET SPINAL SLL, 25G 10/CUTIE
SPICC0012	Traiect personalizat pentru injective, de unica folosinta
922/025/0345	25G SET SPINAL PERSONALIZAT

S.C. GRAZY PRICE MEDICAL IMPORT EXPORT S.R.L. Conform cu originalul

MINISTERUL JUSTIȚIEI MUȘUROIA MIRELA Ad. Nr. 2769 TRADUCĂTOR AUTORIZAT

Prima emitere: **2017-06-16** Data: **2017-06-16** Data expirării: **2022-06-15**

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Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

Data	Numar de referinta	Actiune
Curenta	10166127	Prima editie. Transfer de la alt organ de certificare si inoire certificat.

****

Subsemnata **MUSUROIA MIRELA,** traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015

S.C. GRAZY PRICE MEDICAL IMPORT EXPORT S.R.L. Conform cu originalul

Prima emitere: **2017-06-16**

MINISTERUL JUSTIȚIEI MUȘUROIA MIRELA Aut. Nr. 2769 Engleză-Franceză TRADUCĂTOR AUTORIZAT

Data expirării: **2022-06-15**

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Professional. Flexible. Medical Only.

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Smiths Medical ASD, Inc.
330 Corporate Woods Parkway
Vernon Hills, IL 60061-3107
USA

has introduced, applies and maintains a Quality Management System in the area of:

Manufacture and final inspection of
- **water and saline solutions for inhalation**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2012 + AC:2012

This certificate is valid from 08 July 2015 until 07 July 2018

Report No.: 2708FS19F
Process No.: QS – 2708
Certificate No.: 2708GB438150706

Hamburg, 06 July 2015

MEDCERT Certification Body
(Rainer Klatt)

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

Certificate of Registration

This is to certify that the quality management system of

SMITHS MEDICAL ASD INC.

1265 Grey Fox Road, St Paul, Minnesota, 55112, USA
And at: 3350 Granada Avenue North, Oakdale Minnesota, 55128, USA
And at: 3400 Granada Avenue North, Oakdale Minnesota, 55126, USA
And at: 6000 Nathan Lane North, Minneapolis, Minnesota, 55442, USA

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

EN ISO 13485:2012

The quality management system is applicable to:

Main Site: 1265 Grey Fox Road, St. Paul, Minnesota, 55112, USA:
The design, manufacture of implantable access systems, infusion sets, needles, introducer sets, percutaneous catheters, dialysis catheters, medication cassette reservoirs, administration sets, extension sets, detectors, software suite, communication systems, syringe drivers, peripherally inserted central catheters, heamodialysis catheters, stopcocks, filters, , air detector clamps, convective warming blankets, disposables and accessories, spironmeters, fluid warming accessories and disposables, temperature monitoring sensors.

See appendix for additional scopes

Certificate Number:	**058-02 B**
Initial Certification Date:	**28 October 2004**
Certificate Effective Date:	**21 April 2016**
Certificate Expiry Date:	**20 April 2019**

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd

UKAS MANAGEMENT SYSTEMS
061

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited. AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061. In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.

The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 9001:2008-UKAS-EN-LT-P-04.jan.12

Intertek Intertek Intertek

Appendix to Certificate of Registration 058-02 B

This appendix identifies the locations by the management system of:

SMITHS MEDICAL ASD INC.

Additional Site: 3350 Granada Avenue North, Oakdale, Minnesota, 55128, USA:
The design, manufacture, and servicing of hand held pulse oximeter, volumetric pumps, medical gas and vital signs monitoring equipment and accessories, convective warming systems, temperature management systems (disposables and accessories), pulse oximeter sensors, irrigation warming set (disposable and accessories), positive airway pressure therapy systems, vibratory positive expiratory pressure therapy systems, nebulizers, and pressure cuffs..

Additional Site: 3400 Granada Avenue North, Oakdale, Minnesota, 55128, USA
The design, manufacture and servicing of syringe infusion pumps, ambulatory infusion pumps. Sterile device subassembly in ISO Class 8 cleanroom, warehousing and distribution.

Additional Site: 6000 Nathan Lane North, Minneapolis, Minnesota, 55128, USA
Document Control, Post Market Risk Management, Customer Complaints, Global Sourcing, Regulatory Affairs

Initial Certification Date: 28 October 2004
Certificate Effective Date: 21 April 2016

Brian Johnson ~ Authorized Signatory

Certificat de înregistrare

Intertek

Se confirmă prin prezenta că sistemul de management al calităţii al

SMITHS MEDICAL ASD INC.

1265 Grey Fox Road, St Paul, Minnesota, 55112, SUA
Şi: 3350 Granada Avenue North, Oakdale Minnesota, 55128, SUA
Şi: 3400 Granada Avenue North, Oakdale Minnesota, 55126, SUA
Şi: 6000 Nathan Lane North, Minneapolis, Minnesota, 55442, SUA

a fost evaluat în înregistrat de AMTAC Certification Services Limited ca fiind conform cerinţelor:

EN ISO 13485:2012

Sistemul de management al calităţii se aplică pentru:
Adresă principală: 1265 Grey Fox Road. St. Paul Minnesota, 55112, SUA:

Proiectarea, producţia de sisteme de acces implantabile, seturi pentru infuzie, ace, seturi introducătoare, catetere percutanate, catetere pentru dializă, rezervoare cu casete pentru medicaţie, seturi pentru administrare, seturi de extensie, detectoare, pachete software, sisteme de comunicaţii, conducătoare pentru seringi, catetere centrale cu introducere periferică, catetere pentru hemodializă, ventile, filtre, cleme pentru detectoare de aer, pături cu încălzire prin convecţie, consumabile şi accesorii, spirometre, accesorii şi consumabile pentru încălzirea fluidelor, senzori de monitorizarea temperaturii.

A se vedea anexa pentru aplicaţii suplimentare

Numărul certificatului: 058-02 B
Data primei certificări: 28.10.04
Data efectivă a certificatului: 21.04.16
Data expirării certificatului: 20.04.19

Prin emiterea acestui certificat, Intertek nu îşi asumă responsabilitate decât faţă de client şi numai în conformitate cu contractul convenit pentru certificare. Valabilitatea acestui certificat depinde de menţinerea de către firmă a sistemului în conformitate cu cerinţele Intertek pentru certificarea sistemelor. Valabilitatea poate fi confirmată prin email la certificate.validation@intertek.com sau prin scanarea codului din partea dreaptă cu un telefon mobil. AMTAC Certification Services Limited este deţinută de AMTAC Certification Services Holdings Limited, care este o subsidiară deţinută integral de Intertek UK Holdings Limited. AMTAC Certification Services Limited este organism acreditat conform UKAS, număr de identificare 061. Prin emiterea acestui certificat, AMTAC nu îşi asumă răspundere decât faţă de Client şi în conformitate cu termenii şi condiţiile convenite.
Certificatul rămâne proprietatea Intertek, căreia trebuie să îi fie returnat la cerere.

MATECIUC ALIN BOGDAN
TRADUCĂTOR AUTORIZAT
Nr. 2826

Anexă la Certificatul de Înregistrare 058-02 B

Intertek

Această anexă identifică adresele sistemului de management al:

SMITHS MEDICAL ASD INC.

Adresă suplimentară: 3350 Granada Avenue North, Oakdale, Minnesota, 55128, SUA:

Proiectarea, producţia şi service-ul oximetrelor de puls manuale, pompelor volumetrice, echipamente şi accesorii pentru monitorizarea semnelor vitale şi gazelor medicale, sisteme de încălzire prin convecţie, sisteme de management al temperaturii (consumabile şi accesorii), senzori pentru oximetre de puls, seturi pentru încălzirea irigării (consumabile şi accesorii), sisteme de terapie prin presiunea pozitivă a căilor aeriene, sisteme de terapie prin presiune expiratorie pozitivă cu vibraţii, nebulizatoare şi tuburi de presiune.

Adresă suplimentară: 3400 Granada Avenue North, Oakdale, Minnesota, 55128, SUA

Proiectarea, producţia şi service-ul pompelor de infuzie pentru seringi, pompelor de infuzie ambulatorii. Subansamble pentru dispozitive sterile din clasa 8 ISO, sterilizare, depozitare şi distribuţie.

Adresă suplimentară: 6000 Nathan Lane North, Minneapolis, Minnesota, 55128, SUA

Controlul documentelor, managementul riscului post-vânzare, Reclamaţii clienţi, achiziţie globală, proceduri de reglementare

Data primei certificări: 28.10.04
Data efectivă a certificatului: 21.04.16

MATECIUC ALIN BOGDAN
TRADUCĂTOR AUTORIZAT
Nr. 2826